Supreme Court, U.S.
FILED

No. 03 1327 MAR 15 2004

IN THE

Supreme Court of the United States

DANIEL C. FANNING, individually and as Class Representative,

Petitioners,

v.

UNITED STATES OF AMERICA, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

ARNOLD LEVIN
Counsel of Record
MICHAEL D. FISHBEIN
ZANETTA MOORE-DRIGGERS
LEVIN, FISHBEIN, SEDRAN & BERMAN
510 Walnut Street, Suite 500
Philadelphia, PA 19106
(215) 592-1500

Attorneys for Petitioners

186312

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTION PRESENTED

Does 42 U.S.C. § 405(h), incorporated into the Medicare Act by 42 U.S.C. § 1395ii, preclude federal question jurisdiction under 28 U.S.C. § 1331, over an action asserting constitutional challenges to the administrative adjudication procedure utilized by the United States government to seek Medicare reimbursement from private citizens who received distribution from a tort settlement fund, where the adjudication effected a deprivation of property without due process of law.

PARTIES TO THE PROCEEDINGS

The Petitioners, who appeared before the United States Court of Appeals for the Third Circuit at Docket No. 01-3366 (3d Cir.), are Daniel Fanning, individually and as Class Representative.

The respondents to this Petition, who appeared before the Third Circuit at Docket No. 01-3366 (3d Cir.), and are not set forth in the caption are: the United States Department of Defense; the United States Department of the Army; the United States Department of the Navy; the United States Department of the Air Force; the United States Indian Health Service; the United States Department of Veterans Affairs; Donald H. Rumsfeld, as Secretary of Defense; Gregory A. Dahlberg, The Honorable, as Acting Secretary of the Army; Grodon R. England, The Honorable substituted, as Secretary of the Navy; James G. Roche, The Honorable Dr., as Secretary of the Air Force; Charles W. Grim D.D.S, M.H.S.A., as Director of the Indian Health Service; Anthony J. Principi, The Honorable, as Secretary of the Department of Veterans Affairs; the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration); the United States Department of Health and Human Services; Tommy G. Thompson, in his capacity as Secretary of the United States Department of Health and Human Services; and Thomas Scully, in his capacity as Administrator of the Centers for Medicare and Medicaid Services (formerly Administrator of the Health Care Financing Administration).

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STATEMENT OF JURISDICTION

The judgment of the Court of Appeals was filed on October 10, 2003. The Order of the United States Court of Appeals for the Third Circuit, denying Fanning's timely Petition for Rehearing *En Banc*, dated December 16, 2003, is reprinted in the Appendix beginning at page 80a. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Due Process Clause of the United States Constitution provides in relevant part: "No person shall . . . be deprived of life, liberty, or property, without due process of law. . . ." U.S. Const. Amend. V. The provisions of 42 U.S.C. §§ 405(g), 405(h), 1395ii, and 1395y(b)(2) are reproduced in the Appendix beginning at 83a.

STATEMENT OF THE CASE

This case raises important, recurring questions relating to whether the government may avoid judicial review of pre-hearing deprivations of property interests in federally administered benefits programs, in violation of the United States Constitution.

This case arises from the Government's effort to obtain reimbursement of medical expenses from crippled and disabled class members who received partial distributions from a limited fund class action settlement with AcroMed Corporation in *In re Orthopedic Bone Screw Product Liability Litigation,* No. 97-cv-381 ("*Bone Screw Litig.*").[1] The Government claimed it was entitled to reimbursement under the Medicare Secondary Payer statute, 42 U.S.C. § 1395y(b)(2) ("MSP"), and sought to appropriate the reimbursement through threats of an imminent pre-hearing attachment. That effort to recover from the class members is contrary to law. The threat of a pre-hearing levy, used by the Government against class members who suffer from disabling spinal injuries, is unconstitutional, as violative of the Due Process Clause, and class members have no administrative recourse to address this violation.

On March 1, 2001, Fanning filed a motion in the *Bone Screw Litig.*, to require distribution of the settlement proceeds. On that same date, acting in a representative capacity, Fanning filed an action in the United States District Court for the Eastern District of Pennsylvania, seeking a judgment declaring that the Government had no right on

1. One aspect of this complex mass tort action has previously been subject to review by this court. *See Buckman v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001).

account of the AcroMed settlement to recover payments previously made by the Government for medical expenses of the class members, and permanently enjoining the Government from attempting such recovery from the class members. Subsequently, the Government administratively adjudicated its claims against the class members without affording them notice of its alleged claim and an opportunity to be heard concerning it.

The Government sent adjudication letters ("Adjudications") to the members of the plaintiff-class stating that it was entitled to Medicare reimbursement in specified amounts which were supposed to represent the amounts previously paid by Medicare for bone screw-related injuries, to the extent of the class members' recoveries in the *Bone Screw Litigation,* and demanding immediate payment of those amounts. (App. 96a). The Adjudications also threatened a levy on other federal benefits received by class members including the Medicare and Social Security benefits on which many of these disabled class members rely to support and maintain their very existence. (App. 96a). Moreover, they threatened accrual of interest at the confiscatory rate of 13.75%[2] from the date of the letter, if the amount was not paid within sixty days, regardless of whether the class members challenged the de facto levy and requested an administrative hearing. (App. 96a).

Following the Government's action, Fanning filed an amended complaint. Fanning also requested class certification and a preliminary injunction to prevent the

2. The Adjudications impose interest at the rate of 13.75% per annum. In contrast, the federal judgment rate of interest is tied to the yield on treasury bills, which in the last few years has hovered between one and two percent. *See* 28 U.S.C. § 1961 and www.federalreserve.gov.

Government from proceeding with its efforts to administratively adjudicate its claims. The district court had jurisdiction pursuant to 28 U.S.C. § 1331. The Government filed a motion to dismiss the complaint.

On June 29, 2001, the judge in the District Court, the Honorable Louis Bechtle issued an opinion granting the motions for class certification and for a preliminary injunction. The Court found that "the Medicare statutory scheme does not preclude judicial review of the class members' claims." *In re Orthopedic Bone Screw*, 202 F.R.D. 154, 170 (E.D. Pa. 2001). (App. 71a). The Court also found that judicial review was authorized by the Administrative Procedures Act, 5 U.S.C. § 702, *et seq.* *Id.* at 171. (App. 72a). In addition, the Court said that "the class members have established the likelihood of irreparable harm," and that the Plaintiffs "are likely to ultimately succeed on the merits of the Government's MSP claim." *Id.* at 169. (App. 66a).

The Government filed an appeal of the District Court's decision, arguing that the District Court lacked jurisdiction to hear Petitioners' claims because they had not exhausted administrative remedies. On October 10 , 2003, the Third Circuit Court of Appeals reversed the District Court, ruling that the District Court had no federal question jurisdiction. The Third Circuit found that the central issue was whether the AcroMed settlement fund was a self-insured plan, and thus a primary plan under the MSP.[3] *Fanning v. United States*,

3. At the time of the Third Circuit's opinion, there was a circuit split on the question of whether a tort settlement fund was a "self-insured plan" under the MSP such that the Government could recover reimbursement of prior Meidicare expenses paid to treat the (Cont'd)

346 F.3d 386, 400 (3d Cir. 2003). (App. 29a). Therefore, the Third Circuit held "that both the standing and substantive basis for the claim asserted in the amended class action complaint are rooted in, and derived from, the Medicare Act." *Id.* (App. 30a). Thus, the Third Circuit found that 42 U.S.C. § 405(h) compelled

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(Cont'd)
injuries that were the subject of the tort action. The Second and Fifth Circuits rejected the government's argument and held that the government was not entitled to such reimbursement. *See Mason v. American Tobacco Co.*, 346 F.3d 36 (2nd Cir. 2003) and *Thompson v. Goetzmann*, 315 F.3d 457 (5th Cir. 2002), *opinion withdrawn and reissued as amended on other grounds*, 337 F.3d 489 (5th Cir. 2003). The Eleventh Circuit accepted the government's MSP reimbursement argument in *United States v. Baxter Intern. Inc.*, 345 F.3d 866 (11th Cir. 2003). On December 8, 2003, Congress amended the MSP to read that "An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance or otherwise) in whole or in part." The amendments also set forth

> A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means.

However, the validity of the amendments is questionable, given that they were made retroactive, as if they had been included in the enactment of section 953 of the Omnibus Reconciliation Amendments of 1980, a retroactive period of over twenty years. *See United States v. Carlton*, 512 U.S. 26 (1994) amendment retroactive for one (1) year was constitutional where Congress "acted promptly and established only a modest period of retroavticity"); *Pension Benefit Guar. Corp. v. R.A. Gray & Co.*, 467 U.S. 717 (1984) (retroactive effect for five(5) months was constitutional because it was "confined to short and limited period[]).

Petitioners to channel their claims through the agency. *Id.* (App. 30a). The Third Circuit ignored the government's violation of class members' due process rights, both sustantively and as a basis for the exercise of jurisdiction by the District Court.

REASONS FOR GRANTING THE PETITION

I. This Petition Presents A Recurring Issue of Significant National Concern

This issue will continue to arise more frequently, given the current status of mass-tort litigation as part of our legal landscape.[4] The significance of the issue is illustrated by developments in litigation, the government's tactics in asserting its claims, Congressional action, and judicial commentary. Clear guidance from this Court is imperative.

By definition, mass-tort cases involve substantial numbers of people injured by the same product or accident. Along with such litigation come settlement funds that are often made available to compensate injured victims. The government has recently decided to seek Medicare reimbursement from mass-tort or class-action plaintiffs once they obtain distribution of settlement funds, regardless of the distribution amount or whether medical expenses for the class of plaintiffs were calculated in the settlement. In its zeal for monetary recovery, the government, as a matter of institutional practice, tramples upon the constitutional rights of

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4. A few of the current mass-tort, multidistrict litigation cases include *In re Baycol Prod Liab. Litg.*, MDL No. 1431 (D. Minn.); *In re Propulsid Prod. Liab. Litig.*, MDL No. 1355 (E.D. La.); *In re Rezulin Prod. Liab. Litig.*, MDL No. 1348 (S.D.N.Y.); *In re Air Crash at Taipei, Taiwan, on October 31, 2000*, MDL No. 1394 (C.D. Cal.); and *In re Sulzer Orthopedics Inc. Hip Prosthesis and Knee Prosthesis Prod. Liab. Litig.*, MDL No. 1401 (N.D. Ohio).

these victims, by denying them a pre-deprivation hearing. The magnitude of this issue is emphasized in the legislative history of the recent amendments to the MSP, which reflect that the Government expects to recover more than nine billion dollars from the tort recoveries of injured Medicare beneficiaries over the next ten years. Medicare Prescription Drug and Modernization Act of 2003, H.R. 2473, 108th Cong., H.R. Rep. 108-178(II), § 301 (2003).

The Government, through these coercive pre-hearing Adjudications, essentially takes the Medicare beneficiaries property without due process. This is fundamentally unconstitutional. By definition, mass tort victims are citizens who have suffered serious or debilitating injuries, which have rendered them dependent on the Medicare, Social Security and other federal benefits subject to seizure through the Adjudications. An unconstitutional deprivation of their property cannot be undone or fixed after the fact. *Fuentes v. Shevin*, 407 U.S. 67, 81-82 (1972). "If the right to notice and a hearing is to serve its full purpose, then, it is clear that it must be granted at a time when the deprivation can still be prevented." *Id.* at 81.

The MSP amendments make it easier for the government to pursue claims against mass-tort victims, defendants and settlement funds. However, the procedure routinely used by the government to appropriate MSP reimbursement was not addressed by Congress in those recent amendments. That procedure, which operates to deprive citizens of their property without due process, is still unconstitutional. It is simply wrong to coerce immediate payment from citizens based on erroneous adjudications, without affording those citizens a pre-deprivation opportunity to demonstrate that the calculations are mistaken. To, in the same breath, threaten

those citizens, who are poor and disabled, with seizure of federally administered benefits, upon which they are dependent, prior to an opportunity to dispute the claimed debt, is unconscionable. "For when a person has an opportunity to speak up in his own defense, and when the State must listen to what he has to say, substantively unfair and simply mistaken deprivations of property interests can be prevented." *Fuentes*, 407 U.S. at 81.

The unconstitutionality of the government's actions cannot be ignored. Judicial commentary reflects the recurring nature of the issue presented here. In *United States v. Baxter Intern.*, 345 F.3d 866 (11th Cir. 2003), the Eleventh Circuit Court of Appeals indicated that expansion of the MSP statute has made "Medicare secondary to a greater array of primary coverage sources. . . ." *Id.* at 877. The Eleventh Circuit also found that "any payment that Medicare does make is secondary and is subject to reimbursement from sources of primary coverage under the statute." *Id.* at 886. Thus, the government has increasing opportunities to attempt seizures of private property. Further, the government's tactics have repeatedly been questioned. *See e.g. Fanning*, 346 F.3d at 25, n.17 (government letters unnecessarily callous and threatening); *Waters v. Farmers Texas County Mut. Ins. Co.*, 9 F.3d 397, 400-01 (5th Cir. 1993) (court expressed disappointment with "the government's overreaching interpretation of its authority under the [MSP]"); *In re Dow Corning Corp.*, 250 B.R. 298, 336 (Bankr. E.D. Mich. 2000) (describing government action as "heavy-handed collection tool").

II. The Administrative Adjudication Of The Government's MSP Claims Violate The Due Process Clause

The Adjudications violate the class members' Constitutional rights. A beneficiary's interest in receiving Medicare benefits, such as the interest affected by the Adjudications here, is a constitutional property interest subject to the protection of the due process clause. *Gray Panthers v. Schweiker*, 652 F.2d 146, 152, n.15, 158, 167-72 (D.C. Cir. 1980); *Zinman v. Shalala*, 835 F. Supp. 1163, 1169 (N.D. Cal. 1993), *aff'd*, 67 F.3d 841 (9th Cir. 1995). Moreover, the Adjudications affect the property interests of class members at least as profoundly as a judgment or the pre-judgment attachments which were subject to due process restraint in cases such as *Connecticut v. Doehr*, 501 U.S. 1, 9-16 (1991); *Fuentes v. Shevin*, 407 U.S. 67, 88 (1972), and *Reardon v. United States*, 947 F.2d 1509, 1517-18 (1st Cir. 1991).

Accordingly, under the Due Process Clause, the Government was obliged to afford the plaintiff-class members the kind of "notice and hearing that are aimed at establishing the validity, or at least the probable validity, of the underlying claim against" them before entering the Adjudications even if they might be undone by a later appeal. *E.g.*, *Fuentes*, 407 U.S. at 97; *Sniadach v. Family Finance Corp.*, 395 U.S. 337, 343 (1969). Fundamental notions of due process dictate that the poor and handicapped class members should have been given notice of the Government claims. Instead, they were sent the coercive Adjudications which purported to be final determinations and threatened attachment of their life sustaining benefits if payment was not made promptly. In fact the Third Circuit recognized that the Adjudications were "unnecessarily callous and threatening" and were "more suggestive of tactics one might attribute to a

less than reputable collection agency rather than to one's own government." *Fanning*, 346 F.3d at 401-02, n.17. (App. 33a-34a).

The Government adjudicated its own claims, and effectively initiated a levy on the property of class members without any advance notice, let alone an opportunity to be heard before the coercive appropriation of their property. This deprived the plaintiff-class members of the opportunity to show that the Government's claims were legally baseless, that they did not receive some or all of the health care items or services, which were the subject of the Adjudications, as a result of injuries related to AcroMed orthopedic bone screws, and that they did not receive the amounts from the AcroMed settlement fund which were set forth as the explicit basis for the Adjudications. None of the factors set forth in *Mathews v. Eldridge*, 424 U.S. 319 (1976), justifies this deprivation.

Pursuant to *Matthews* the factors to be considered when determining the due process issues in a State deprivation of property are: "the private interest that will be affected by the official action;" "the risk of an erroneous deprivation of such interest . . . and the probable value, if any, of additional or substitute procedural safeguards;" and "the Government's interest, including . . . the fiscal and administrative burdens that the additional or substitute procedural requirement would entail." *Matthews*, 424 U.S. at 335. Consideration of the private interest affected by the official action certainly points to the necessity of due process protection here. The interest of class members in Social Security, Railroad Retirement, Medicare, and other benefits upon which they rely for sustenance, are affected by the Government's Adjudications. These are extreme deprivations. The Supreme Court has held

that "even the temporary or partial impairment to property rights that attachments, liens, and similar encumbrances entail are sufficient to merit due process protection." *Doehr*, 501 U.S. at 12.

The risk of erroneous deprivation here is great. As evidenced by the testimony and affidavits presented to the District Court, the Adjudications are often wrong.[5] The amounts demanded include charges for care not related to treatment with the orthopedic bone screws that were the subject of the litigation, services for which Medicare did not even pay, services for which Medicare was already reimbursed, and services which were never received by class members. However, before having the opportunity to dispute these charges, class members were threatened with accrual of confiscatory amounts of interest on the Government's claimed debt, having their life sustaining benefits seized, and having the debt assigned to the Department of the Treasury for collection efforts – all without the prospect for a hearing before any of these deprivations were effectuated. The probable value of safeguards, preventing prejudgment interest accrual and prejudgment deprivation of property, is substantial. "A later hearing . . . would not cure the temporary deprivation that an earlier hearing might have prevented." *Doehr*, 501 U.S. at 15. Regarding financial or administrative burdens on providing the pre-attachment hearing, as this Court held in *Doehr* "the State cannot seriously plead additional financial or administrative burdens involving predeprivation hearings when it already claims to provide an immediate post-deprivation hearing." *Doehr* at 16. Likewise, that is not an issue here as the Government argued below that

5. A representative sample of the testimony and affidavits is included in the Appendix, beginning at 101a.

the class members' "appeal" rights afford them the possibility of a post-deprivation hearing.

Thus, the Government violated the class members' due process rights, and it did so deliberately as part of a heavy-handed collection strategy. *See Dow Corning*, 250 B.R. at 336, n.21 (noting the government's use of MSP as a "heavy-handed collection tool"). Such behavior is the hallmark of injustice. Petitioners had a right to seek a judicial remedy for the government's unconstitutional acts.

The present matter is not one which falls within the scope of Section 1395ff and the concomitant review provisions of Sections 405(h) & (g). The Adjudications at issue here would strip disabled class members of the amounts which they require for their medical care and support without a prior opportunity for judicial review. Thus, as a practical matter, the Adjudications would impair the class members' rights to judicial review so as to make Section 405(h) inapplicable.

CONCLUSION

Because the government's collection of MSP "Reimbursements" is a recurring issue of national importance, and such collection actions constitute a violation of the Due Process Clause, this Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

ARNOLD LEVIN
Counsel of Record
MICHAEL D. FISHBEIN
ZANETTA MOORE-DRIGGERS
LEVIN, FISHBEIN, SEDRAN & BERMAN
510 Walnut Street, Suite 500
Philadelphia, PA 19106
(215) 592-1500

Attorneys for Petitioners

APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT FILED OCTOBER 10, 2003

UNITED STATES COURT OF APPEALS
THIRD CIRCUIT

No. 01-3366

Argued June 10, 2002.

Opinion Filed: Oct. 10, 2003.

Daniel C. FANNING, Individually, and as Representative of a Class of Persons Similarly Situated

v.

THE UNITED STATES of America; United States Health Care Financing Administration; United States Department of Defense; United States Department of Health and Human Services; United States Department of the Army; United States Department of the Navy; United States Department of the Air Force; United States Indian Health Service; United States Department of Veterans Affairs; Michael McMullen, Mrs., as Acting Deputy Administrator of the United States Health Care Financing Administration; Donald H. Rumsfeld, as Secretary of Defense; Tommy G. Thompson, as Secretary of the Department of Health and Human Services; Gregory R. Dahlberg, the Honorable, as Acting Secretary of the Army; Robert B. Pirie, Jr., the Honorable, as Acting Secretary of the Navy; Lawrence Delaney, the Honorable Dr., as Secretary of the Air Force; Michael H. Trujillo,

Appendix A

M.D., M.P.H., as Director of the Indian Health Service; Anthony J. Principi, the Honorable, as Secretary of the Department of Veterans Affairs; Robert E. Welsh, Jr., Esquire, as Administrator of the AcroMed Settlement Agreement; PNC Bank, N.A., as Trustee for the Acromed Settlement Agreement United States of America, the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), the United States Department of Health and Human Services, Tommy G. Thompson in his capacity as Secretary of the United States Department of Health and Human Services, and Thomas Scully in his capacity as Administrator of the Centers for Medicare and Medicaid Services (formerly Administrator of the Health Care Financing Administration),

Appellants

Before: SLOVITER, ROTH, and McKEE, Circuit Judges.

OPINION OF THE COURT

McKEE, Circuit Judge.

This litigation is the aftermath of an attempt by the Health Care Financing Administration ("HCFA") (now known as the Centers for Medicare and Medicaid Services ("CMS")), to obtain reimbursement under the Medicare as Secondary Payer statute, 42 U.S.C. § 1395y(b)(2). HCFA attempted to collect from a settlement trust fund for Medicare payments that had been made to AcroMed settlement class members for various medical expenses arising from injuries the

settlement class members allegedly suffered as a result of the use of orthopedic bone screws manufactured by AcroMed. Daniel Fanning filed an amended complaint for declaratory and injunctive relief in an attempt to prevent the HCFA from obtaining Medicare reimbursement. Fanning filed the complaint on his own behalf and on behalf of the class in an attempt to prevent the HCFA from obtaining any of the proceeds of the settlement fund.[1]

The district court certified the class and granted preliminary relief enjoining the HCFA from attempting to obtain MSP reimbursement from the settlement trust fund. However, because we find that the district court did not have federal question jurisdiction, we will reverse and remand with instructions to dismiss the amended complaint.

I. BACKGROUND

A. THE MEDICARE AS SECONDARY PAYER STATUTE

Prior to 1980, Medicare generally paid for medical services whether or not the recipient was also covered by another health plan. *See* Social Security Amendments of 1965, Pub.L. No. 89-97, § 1862(b), 79 Stat. 286. However, beginning in 1980, Congress enacted a series of cost cutting amendments to the Medicare program. These amendments are collectively known as the Medicare as Secondary Payer ("MSP") statute or the MSP provisions. *See New York Life*

1. Fanning's amended complaint invoked the district court's federal question jurisdiction pursuant to 28 U.S.C. § 1331.

Ins. Co. v. United States, 190 F.3d 1372, 1374 (Fed.Cir.1999).[2]

The MSP statute was designed to curb skyrocketing health costs and preserve the fiscal integrity of the Medicare system. *See Zinman v. Shalala,* 67 F.3d 841, 845 (9th Cir.1995); H.R.Rep. No. 96-1167, at 352 (1980). The MSP attempted to lower overall federal Medicare disbursements by requiring Medicare beneficiaries to exhaust all available insurance coverage before looking to Medicare's coverage. *See United States v. Rhode Island Insurers' Insolvency Fund,* 80 F.3d 616, 618 (1st Cir.1996). The MSP assigns primary responsibility for medical bills of Medicare recipients to private health plans when a Medicare recipient is also covered by private insurance. These private plans are therefore considered "primary" under the MSP and Medicare acts as the "secondary" payer responsible only for paying amounts not covered by the primary plan.[3] *Blue Cross and Blue Shield of Texas v. Shalala,* 995 F.2d 70, 73 (5th Cir.1993).

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2. The amendments have been codified at 42 U.S.C. § 1395y(b).

3. "Before 1980, if a Medicare beneficiary had an alternate source of payment, such as private insurance or an employee group health plan, Medicare was the primary payer, and the health plan was the secondary payer, liable only for the costs that remained after Medicare made its payments. Private insurers even wrote this practice into their health insurance contracts. Congress enacted the MSP statute to reverse the order of payment in cases where Medicare beneficiaries have an alternate source of payment for health care." *Blue Cross and Blue Shield of Texas,* 995 F.2d at 73 (citations omitted).

Appendix A

Congress established two principal directives to achieve this objective. First, the MSP bars Medicare payments where "payment has already been made or can reasonably be expected to be made promptly (as determined in accordance with regulations)" by a primary plan. 42 U.S.C. § 1395y(b)(2)(A) (parenthetical in original). "Prompt" payment is defined in the applicable regulations as payment made within 120 days of either the date on which care was provided or when the claim was filed with the insurer, whichever is earlier. *See* 42 C.F.R. §§ 411.21, 411.50. The MSP defines a "primary plan" as "a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance [.]" 42 U.S.C. § 1395y(b)(2)(A)(ii) (parenthetical in original). This provision "is intended to keep the government from paying a medical bill where it is clear an insurance company will pay instead." *Evanston Hosp. v. Hauck,* 1 F.3d 540, 544 (7th Cir.1993) (citation omitted).

Second, the MSP provides that when Medicare makes a payment that a primary plan was responsible for, the payment is merely conditional and Medicare is entitled to reimbursement for it. 42 U.S.C. § 1395(y)(b)(2)(B); *Blue Cross and Blue Shield of Texas v. Shalala,* 995 F.2d 70, 73 (5th Cir.1993) (2002). Section 1395y(b)(2)(B) provides:

> Any payment under this subchapter with respect to any item or service to which subparagraph (A) applies shall be conditioned on reimbursement to the appropriate Trust Fund established by this subchapter when notice or other information is

> received that payment for such item or service has been or could be made under such subparagraph.

42 U.S.C. § 1395y(b)(2)(B)(i). Medicare payments are subject to reimbursement to the appropriate Medicare Trust Fund once the government receives notice that a third-party payment has been or could be made with respect to the same item or service.[4] *Id.*

B. THE ACROMED LITIGATION

As noted above, the controversy surrounding the Medicare payments at issue here arose from a class action settlement of claims pertaining to orthopedic bone screws manufactured by AcroMed. AcroMed began marketing orthopedic bone screw devices for use in spinal fusion surgery in 1983. By the early part of the 1990s, thousands of individuals who had undergone spinal fusion surgery experienced complications and infirmities that they associated with AcroMed's bonescrews. A flood of product liability suits against AcroMed followed. *See In re Orthopedic Bone Screw Products Liability Litigation,* 176 F.R.D. 158, 165 (E.D.Pa.1997). In 1994, the Judicial Panel on Multidistrict Litigation transferred all of the pending cases to the United States District Court for the Eastern District of

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4. If MSP reimbursement is not made, the MSP authorizes the government to bring an action against "any entity which is required or responsible . . . to make payment . . . under a primary plan" and against "any other entity (including a physician or provider) that has received payment from that entity." 42 U.S.C. § 1395y(b)(2)(B)(ii). The MSP also gives the government a separate right of subrogation. 42 U.S.C. § 1395y(b)(2)(iii).

Pennsylvania for pre-trial proceedings. *Id.* On January 8, 1997, Daniel Fanning, acting as a class representative, reached a settlement with AcroMed on behalf of the class. *Id.* Pursuant to the terms of that settlement, AcroMed transferred $100 million into a trust fund for distribution to class members who qualified for payment in accordance with a procedure to be established by the court.[5] *Id.* at 165-166.

Since members of the settlement class had previously received Medicare payments for medical expenses allegedly stemming from injuries caused by AcroMed's bone screws, the government filed a Statement of Interest in the district court after learning of the proposed AcroMed settlement. In that Statement of Interest, the government stated that, pursuant to the "secondary payer" provisions of the MSP, it intended to recover amounts Medicare had paid for the class members' medical care.

When efforts to settle the government claims broke down, the government sent letters to the approximately 1,800 members of the settlement class demanding repayment of the amounts Medicare had paid for medical treatment. The letters gave each class member 60 days to repay the amount set forth in each letter and warned that if the amount remained unpaid after 60 days, interest would accrue at the rate of 13.75% per annum until the debt was paid, regardless of whether a waiver of recovery request or administrative appeal was pending. The letters also told the class members

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5. In addition to the $100 million, AcroMed agreed to "assign the proceeds of virtually all of its insurance policies to the settlement fund." 176 F.R.D. at 166.

that if they did not pay, Medicare could recover the outstanding balance from other federal benefits the individual plaintiff might otherwise be entitled to including additional Medicare payments, Social Security benefits and Railroad Retirement benefits. The letters similarly threatened that delinquencies would be reported to the Treasury Department for offset against any other federal payments the class members might otherwise receive. On March 21, 2001, Fanning filed an amended complaint alleging that payments from the AcroMed settlement are not the type of payments that give the government a right to reimbursement under the MSP. The amended complaint sought a permanent injunction barring the government from taking any action to enforce the rights asserted under the MSP. Concomitantly, Fanning filed a motion for a preliminary injunction and a motion for class certification.

The government responded with a motion to dismiss for lack of jurisdiction, arguing that 42 U.S.C. § 405(h) requires exhaustion of administrative remedies before claims that arise under the Medicare Act could be subjected to judicial review.[6]

The district court denied the government's motion to dismiss, certified the class and entered a preliminary injunction barring the government from taking any action to obtain reimbursement for Medicare payments from the class members. *In re Orthopedic Bone Screw Products Liability Litigation (Fanning v. United States)*, 202 F.R.D. 154 (E.D.Pa.2001). The court rejected the government's claim

6. The government also opposed the motions for a preliminary injunction and for class certification.

that the court lacked federal question jurisdiction under 42 U.S.C. § 405(h). The court found that § 405(h) did not apply to the settlement class members because they were not trying to recover Medicare benefits. Rather, in the court's view, the class members were attempting to enjoin collection of benefits the government had already paid. *Id.* at 170. This appeal followed.

II. DISCUSSION—FEDERAL QUESTION JURISDICTION

We have appellate jurisdiction over the district court's grant of preliminary injunctive relief pursuant to 28 U.S.C. § 1292(a)(1). However, the government renews its argument that the district court lacked jurisdiction because of the failure to exhaust administrative remedies. Therefore, before we can address the merits of the government's appeal, we must determine if the district court had jurisdiction over Fanning's amended class action complaint.[7]

It is obvious that when another insurer makes a payment for medical services Medicare has already paid for, a duplicate payment results. In the absence of reimbursement to Medicare, the duplicate payment is an overpayment of Medicare under the MSP. *See* 42 C.F.R. § 405.704(b)(13); *Buckner v. Heckler,* 804 F.2d 258, 259 (4th Cir.1986).

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7. A court of appeals has the obligation, not only to satisfy itself that it has appellate jurisdiction, but also to satisfy itself of the jurisdiction of the district court under review. *Dole v. Trinity Industries, Inc.*, 904 F.2d 867, 870 (3d Cir.1990). Our standard of review of the district court's determination that it had jurisdiction is plenary. *Id.*

As we have discussed, the MSP allows the Secretary to obtain reimbursement of the overpayment. 42 U.S.C. §§ 1395y(b)(2)(A)(ii), 1395y(b)(2)(B)(ii). However, a beneficiary who disagrees with the Secretary's determination that an overpayment of Medicare benefits has been made on his or her behalf is entitled to a hearing before the Secretary as provided in 42 U.S.C. § 405(b). *See* 42 U.S.C. § 1395ff(b)(1). If the beneficiary is dissatisfied with the Secretary's final decision after a hearing, the beneficiary is entitled to judicial review of that decision as provided in 42 U.S.C. § 405(g).[8] *See Id.*

8. 42 U.S.C. § 405(g) provides in relevant part:

> Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. . . . As part of the Commissioner's answer the Commissioner . . . shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a rehearing. . . . The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil action. Any action instituted in accordance with this subsection shall survive

(Cont'd)

Appendix A

The AcroMed settlement class members did not use the administrative procedure to challenge the government's efforts to obtain MSP reimbursement from the settlement trust fund. Instead, as noted above, Fanning filed an amended class action complaint pursuant to 28 U.S.C. § 1331 against various government defendants seeking class certification and injunctive relief to prevent the government from seeking reimbursement of the alleged Medicare overpayments. As noted, the government moved, *inter alia,* to dismiss the amended complaint for lack of jurisdiction; however, the district court denied the government's motion to dismiss. The government's argument that the district court lacked jurisdiction is based on 42 U.S.C. § 405(h), a section of the Social Security Act that is made applicable to the Medicare Act by 42 U.S.C. § 1395ii.[9] Section 405(h), captioned "Finality of Commissioner's decision," reads:

> The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the

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(Cont'd)

> notwithstanding any change in the person occupying the office of Commissioner of Social Security or any vacancy in such office.

42 U.S.C. § 405(g).

9. The Medicare Act, 42 U.S.C. §§ 1395-1395zz, is Title XVIII of the Social Security Act. Section 1395ii of the Medicare Act makes § 405(h) applicable to the Medicare Act "to the same extent as" it applies to the Social Security Act.

> Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. *No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346* [federal defendant jurisdiction] *of Title 28 to recover on any claim arising under this subchapter.*

42 U.S.C. § 405(h) (emphasis added). The government contends that the district court lacked jurisdiction over Fanning's amended class action complaint because § 405(h) requires exhaustion of administrative remedies before claims that arise under the Medicare Act may be subject to judicial review. However, as is explained below, we believe that the technically correct argument is that § 405(h) bars federal question jurisdiction of Fanning's class action complaint and requires that the class members "must proceed instead through the special review channel that the Medicare statutes create." *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 5, 120 S.Ct. 1084, 146 L.Ed.2d 1 (2000).

Section 405(h) contains three sentences, but it is the third sentence that is critical to our jurisdictional inquiry. It reads: "No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 [federal defendant jurisdiction] of Title 28 to recover on any claim arising under this subchapter." If Fanning's class action complaint asserts a claim that "aris [es] under" the Medicare Act, then the third sentence of § 405(h) precludes the district court from

exercising federal question jurisdiction over it. Although the issue of whether a claim arises under a particular statute appears at first glance to require nothing more than a reading of the statute, our analysis of whether the class action complaint alleges a "claim arising under" the Medicare Act requires us to first examine four cases in which the Supreme Court discussed the operation and meaning of § 405(h) before relying solely on the "plain text" of the statute.

The first is *Weinberger v. Salfi*, 422 U.S. 749, 95 S.Ct. 2457, 45 L.Ed.2d 522 (1975). There, a deceased wage earner's widow and step-child challenged the Social Security Act's requirement of a nine-month long prior relationship with the deceased wage earner as a condition of receiving survivor's benefits. Concetta Salfi married Londo Salfi on May 27, 1972. In spite of Londo's apparent good health, he suffered a heart attack less than a month later and died on November 21, 1972, less than six months after the marriage. His widow filed applications for mother's insurance benefits for herself and her daughter by a previous marriage. However, the applications were denied by the Social Security Administration, both initially and on reconsideration at the regional level, solely on the basis of the Act's duration-of-relationship provisions.

The widow and other named plaintiffs then filed an action in the district court, "principally relying on 28 U.S.C. § 1331 for jurisdiction," challenging the duration-of-relationship provision on due process and equal protection grounds. 422 U.S. at 755, 95 S.Ct. 2457. The widow also sought to represent a class of all widows and stepchildren who had been denied benefits based solely on the Act's duration-of-

relationship provisions. The widow and the named plaintiffs alleged partial exhaustion of their claims, but made no similar allegations with regard to the claims of other class members. On cross-motions for summary judgment, a three-judge district court panel held that the duration-of-relationship provision was unconstitutional, certified the class and enjoined the Social Security Administration from denying benefits on the basis of the duration-of-relationship provision.

On appeal, the Supreme Court ultimately concluded that the duration-of- relationship provision was constitutional. However, before it reached the merits, the Count noted that it was "confronted . . . by a serious question as to whether the District Court had jurisdiction over th[e] suit." 422 U.S. at 756, 95 S.Ct. 2457. It is, of course, that jurisdictional discussion that is relevant to our inquiry.

The Court began its jurisdictional inquiry by noting that the third sentence of § 405(h) "[o]n its face, . . . bars district court federal-question jurisdiction over suits, such as this one, which seek to recover Social Security benefits." *Id.* at 756-757, 95 S.Ct. 2457. Yet, the widow successfully invoked the district court's federal question § 1331 jurisdiction and the district court considered the third sentence "inapplicable because it amounted to no more than a codification of the doctrine of exhaustion of administrative remedies." *Id.* at 757, 95 S.Ct. 2457. Therefore, the district court found that exhaustion would be futile and waived the requirement. *See Salfi v. Weinberger,* 373 F.Supp. 961, 964 (N.D.Cal.1974).

However, the Supreme Court believed that the district court's conclusion that § 405(h) is simply an exhaustion requirement was "entirely too narrow" and held that the third sentence of § 405(h) is more than that. *Id.* at 757, 95 S.Ct. 2457. It wrote:

> That the third sentence of § 405(h) is more than a codified requirement of administrative exhaustion is plain from its own language, which is sweeping and direct and which states that no action shall be brought under § 1331, not merely that only those actions shall be brought in which administrative remedies have been exhausted. Moreover, if the third sentence is construed to be nothing more that a requirement of administrative exhaustion, it would be superfluous. This is because the first two sentences of § 405(h) . . . assure that administrative exhaustion will be required. Specifically, they prevent review of decisions of the Secretary save as provided in the Act, which provision is made in § 405(g). This latter section prescribes typical requirements for review of matters before an administrative agency, including administrative exhaustion. Thus the District Court's treatment of the third sentence of § 405(h) not only ignored that sentence's plain language, but also relegated it to a function which is already performed by other statutory provisions.

Id. at 757-758, 95 S.Ct. 2457. Although the Court made it abundantly clear that the third sentence of § 405(h) was

something more than a mere exhaustion requirement, it did not fully define the reach of that language.

In any event, the Court next addressed a "somewhat more substantial argument" that the third sentence of § 405(h) did not deprive the district court of federal question jurisdiction. *Id.* at 760, 95 S.Ct. 2457. By its terms, the third sentence only concerns actions to recover "on any claim arising" under the Act. Not unexpectedly, the widow argued that her claim was not one arising under the Act, but was rather a claim under the constitution. *Id.* Therefore, the widow concluded, § 405(h) did not prevent the district court from having federal question jurisdiction over her complaint. However, the Court rejected that argument as well. It wrote:

> It would, of course, be fruitless to contend that . . . the claim is one which does not arise under the Constitution, since [the widow's] constitutional arguments are critical to [her] complaint. But it is just as fruitless to argue that this action does not also arise under the Social Security Act. For not only is it Social Security benefits which appellees seek to recover, *but it is the Social Security Act which provides both the standing and the substantive basis for the presentation of their constitutional contentions.* Appellees sought, and the District Court granted, a judgment directing the Secretary to pay Social Security benefits. To contend that such an action does not arise under the Act whose benefits are sought is to ignore both the language and substance of the complaint and judgment. This

> being so, the third sentence of § 405(h) precludes resort to federal-question jurisdiction for the adjudication of appellees' constitutional contentions.

Id. at 760-761, 95 S.Ct. 2457 (emphasis added). The Court also held that the operation of § 405(h) is not limited to "decisions of the Secretary on issues of law or fact." *Id.* at 762, 95 S.Ct. 2457. Rather, § 405(h) "extends to any 'action' seeking to recover on any (Social Security) claim'—*irrespective of whether resort to judicial processes is necessitated by discretionary decisions of the Secretary or by his nondiscretionary application of allegedly unconstitutional statutory restrictions.*" *Id.* (emphasis added). Finally, insofar as constitutional challenges are concerned, the Court found that the Social Security Act "itself provides jurisdiction for constitutional challenges to its provisions." *Id.* Therefore, the Court held that "the plain words of the third sentence of § 405(h) do not preclude constitutional challenges."

> They simply require that they be brought under jurisdictional grants contained in the Act, and thus in conformity with the same standards which are applicable to nonconstitutional claims arising under the Act. The result is not only of unquestionable constitutionality, but it is also manifestly reasonable, since it assures the Secretary the opportunity prior to constitutional litigation to ascertain, for example, that the

> particular claims involved are neither invalid for other reasons nor allowable under other provisions of the Social Security Act.

Id. Accordingly, the Court held that § 405(h) barred the claims asserted under the district court's federal question jurisdiction.[10]

The second case is *Heckler v. Ringer,* 466 U.S. 602, 104 S.Ct. 2013, 80 L.Ed.2d 622 (1984), in which the Court reaffirmed *Weinberger v. Salfi* and extended its holding to the Medicare Act. There, four Medicare beneficiaries invoked the district court's federal question jurisdiction and brought an action challenging the Secretary's policy and ruling that no Medicare payments would be provided for a surgical procedure known as a bilateral carotid body resection ("BCBR"). They alleged that the policy and ruling violated the Medicare Act, the Administrative Procedure Act and the Due Process clause. *Id.* at 611 n. 7, 104 S.Ct. 2013. They sought declaratory and injunctive relief, including invalidation of the policy and ruling as well as an order enjoining the Secretary from applying it.

The district court dismissed their complaint for lack of jurisdiction. It held that, in essence, the plaintiffs were claiming an entitlement to benefits for the BCBR procedure

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10. As noted, the widow alleged partial exhaustion of her claims, but made no such allegations as to the class members. For reasons not relevant to our discussion, the Court found that the widow and other named plaintiffs who alleged partial exhaustion could assert their claims in the district court under § 405(g). 422 U.S. at 767, 95 S.Ct. 2457.

and that any challenges to the Secretary's policy and ruling were "inextricably intertwined" with their claim for benefits. *Id.* at 611, 104 S.Ct. 2013. Therefore, the district court concluded that 405(g) with its exhaustion prerequisite provided the sole avenue for judicial review. Because none of the four plaintiffs had satisfied the exhaustion requirement, the district court dismissed their complaint. *Id.* at 612, 104 S.Ct. 2013.

The court of appeals reversed. It concluded that plaintiffs were actually arguing that the policy and ruling were "an unlawful administrative mechanism for determining the awards of benefits." *Id.* The court reasoned that, to the extent that the plaintiffs sought to invalidate the Secretary's method for determining entitlement to benefits, the claim was a procedural one cognizable under § 1331 without any condition of exhaustion. *Id.* The court of appeals also agreed with the district court's conclusion that the plaintiffs had raised a substantive claim for benefits. However, while acknowledging that exhaustion was a prerequisite for a benefits claim under § 405(g), the court of appeals refused to dismiss the complaint based upon its belief that exhaustion would be futile.

The Supreme Court reversed the court of appeals. It agreed with the district court and the court of appeals that the claims were really for benefits, but rejected the court of appeals's attempt to separate the particular claims into procedural claims (i.e., challenges to the Secretary's method of rule making), and substantive claims (i.e., claims for benefits). Rather, in the Supreme Court's view, plaintiffs' procedural claim was "inextricably intertwined" with the

substantive claim. *Id.* at 614, 104 S.Ct. 2013. Accordingly, the Court held that "all aspects of respondent's claim for benefits should be *channeled* first into the administrative process which Congress has provided for the determination of claims for benefits." *Id.* at 614, 104 S.Ct. 2013 (emphasis added). Its explained this "channeling" requirement as follows:

> The third sentence of 42 U.S.C. § 405(h), made applicable to the Medicare Act by 42 U.S.C. § 1395ii, provides that 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all "claims arising under" the Medicare Act. *See Weinberger v. Salfi,* 422 U.S. at 760-761, 95 S.Ct. 2457. Thus, to be true to the language of the statute, the inquiry in determining whether § 405(h) bars federal-question jurisdiction must be whether the claim "arises under" the Act, not whether it lends itself to a "substantive" rather than a "procedural" label. *See Mathews v. Eldridge,* 424 U.S. [319] at 327, 96 S.Ct. 893, 47 L.Ed.2d 18 [1976] (recognizing that federal-question jurisdiction is barred by 42 U.S.C. § 405(h) even in a case where the claimant is challenging the administrative procedures used to terminate welfare benefits).
>
> In *Weinberger v. Salfi,* 422 U.S. at 760-761, 95 S.Ct. 2457, we construed the "claim arising under" language quite broadly to include any claims in which "both the standing and the substantive basis for the presentation" of the

> claims is the Social Security Act. In that case we held that a constitutional challenge to the duration-of-relationship eligibility statute pursuant to which the claimant had been denied benefits, was a "claim arising under" Title II of the Social Security Act within the meaning of 42 U.S.C. § 405(h), even though we recognized that it was in one sense also a claim arising under the Constitution.

Id. at 614-615, 104 S.Ct. 2013. The Court concluded that under *Salfi*'s "broad test," the plaintiffs' claims were not cognizable under federal-question jurisdiction because the Medicare Act provided both the substance and standing for the claims. That is to say, the claims "arise under" the Medicare Act. *Id.* at 615, 104 S.Ct. 2013. Therefore, the third sentence of § 405(h) precluded the district court from having federal question jurisdiction. The only avenue for judicial review was § 405(g). *Id.* at 617, 104 S.Ct. 2013.

The third case relevant to the instant inquiry is *Bowen v. Michigan Academy of Family Physicians,* 476 U.S. 667, 106 S.Ct. 2133, 90 L.Ed.2d 623 (1986), which appeared to limit the holdings of *Salfi* and *Ringer. Michigan Academy* involved a challenge by an association of family physicians to a Medicare regulation which authorized payment of Part B benefits in different amounts for similar services. The district court held that the regulation violated several provisions of the Medicare Act and found it invalid. Therefore, the court did not need to address the physicians' constitutional claims. On appeal, the court of appeals agreed that the regulation was inconsistent with the Act and, therefore, irrational and

invalid. The court of appeals also declined to address the physicians' constitutional claims.

The Secretary did not challenge the decision on the merits on appeal to the Supreme Court. Rather, he renewed the jurisdictional argument that the district court and court of appeals had rejected. He claimed that §§ 1395ff and 1395ii (which, as noted, makes § 405(h) applicable to the Medicare Act) forbid judicial review under the district court's federal question jurisdiction of all questions affecting the amount of benefits payable under Part B of the Medicare program. At the time of the litigation in *Michigan Academy,* § 1395ff of the Medicare Act did not provide any administrative or judicial review of Part B benefit amount determinations. The scheme at that time was as follows: Under Part B, the Secretary contracted with private health insurance carriers to provide benefits, and the Medicare participants voluntarily payed a premium for those benefits. 476 U.S. at 674, 106 S.Ct. 2133. Although it was federally subsidized, Part B coverage was an option intended to supplement mandatory institutional health benefits such as coverage for hospital expenses covered by Part A. *Id.* at 674-675, 106 S.Ct. 2133. Individuals aggrieved by delayed or insufficient payment with respect to Part B benefits were entitled to a hearing by the *private carrier,* subject to an amount-in-controversy requirement. In comparison, an aggrieved individual under Part A was entitled to a hearing by the Secretary and to judicial review, also subject to an amount-in-controversy requirement. *Id.* at 675, 106 S.Ct. 2133.

In deciding the case, the Court noted that the "strong presumption" in favor of judicial review of administrative

action, *Id.* at 670, 106 S.Ct. 2133, can only be overcome by congressional intent evidenced by "specific language," *Id.* at 673, 106 S.Ct. 2133, or by "inferences of intent drawn from the statutory scheme as a whole." *Id.* at 673 n. 4, 106 S.Ct. 2133. Applying those principles, the Court found that the Act and its legislative history demonstrated a Congressional intention to "bar judicial review only of determinations of the amount of benefits to be awarded under Part B." *Id.* at 678, 106 S.Ct. 2133. As noted, Part B determinations were delegated to private insurance carriers. However, the Court concluded that "those matters which Congress did *not* leave to be determined in a 'fair hearing' conducted by the carrier—including challenges to the validity of the Secretary's instructions and regulations—are not impliedly insulated from judicial review by . . . § 1395ff."[11] *Id.* (emphasis in original).

The Court also rejected the government's argument that the third sentence of § 405(h), as interpreted by *Salfi* and *Ringer,* barred federal question jurisdiction over the family physicians' challenge to the Secretary's regulation. It wrote:

> Section 405(h) does not apply on its own terms to Part B or the Medicare program, but is instead incorporated *mutatis mutandis* by § 1395ii. The legislative history of both the statute establishing the Medicare program and the 1972 amendments thereto provides specific evidence of Congress'

11. The Court also noted that the Act's exhaustion requirement could not apply to the family physicians' challenge to the regulation because "there is no hearing, and thus no administrative remedy, to exhaust." 476 U.S. at 673 n. 4, 106 S.Ct. 2133.

> intent to foreclose review only of "amount determinations"—i.e., those "quite minor matters" remitted finally and exclusively to adjudication to private insurance carriers in a "fair hearing." By the same token, matters which Congress did *not* delegate to private carriers, such as challenges to the validity of the Secretary's instructions and regulations, are cognizable in courts of law.

Id. at 680, 106 S.Ct. 2133 (citations omitted)(emphasis in original). Accordingly, the Court held that § 405(h) did not prevent the district court from having federal question jurisdiction over the family physicians' complaint.

Michigan Academy created what came to be called the "amount/methodology" distinction, under which pre-enforcement challenges to the method by which Medicare benefits were determined, rather than challenges to the actual amount of the benefits, were not barred by § 405(h). *See* John Aloysius Cogan, Jr., and Rodney A. Johnson, *Administrative Channeling Under the Medicare Act Clarified: Illinois Council, Section 405(h), and the Application of Congressional Intent,* 9 Annals Health L. 125, 134 (2000). However, four months after *Michigan Academy,* Congress amended the Medicare Act to authorize administrative and judicial review of Part B claims meeting certain amount-in-controversy thresholds for services rendered on or after January 1, 1987. The amendment therefore effectively gave Part B claimants the same administrative and judicial remedies Part A claimants had. *Id.* As a result of the amendment, most courts considered *Michigan Academy* a "dead letter," and the "amount/

methodology" distinction was deemed to have been extinguished by Congress. *Id.* (citations omitted).

This set the stage for the final case bearing on our analysis, *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 120 S.Ct. 1084, 146 L.Ed.2d 1 (2000). In *Illinois Council,* an association of nursing homes invoked the district court's federal question jurisdiction and sued the Secretary claiming that certain Medicare health and safety regulations violated various statutes as well as the Constitution. The district court dismissed the suit for lack of jurisdiction, holding that "a set of special statutory provisions creates a separate, virtually exclusive, system of administrative and judicial review of denials of Medicare claims; and it held that one of those provisions [§ 405(h)] explicitly barred a § 1331 suit." 529 U.S. at 5, 120 S.Ct. 1084.

However, the court of appeals reversed and gave new life to *Michigan Academy. Illinois Council on Long Term Care, Inc. v. Shalala,* 143 F.3d 1072 (7th Cir.1998). It found that *Michigan Academy* modified *Salfi* and *Ringer* by limiting their scope to amount determinations rather than pre- enforcement challenges. *Id.* at 1075-1076 ("As the Court read § 1395ii and therefore § 405(h) in *Michigan Academy,* pre-enforcement review of a regulation's validity is not an action to 'recover on' a claim, even when per *Salfi* a constitutional objection to the regulation is a 'claim arising under this subchapter.'").

The Supreme Court, however, reversed the court of appeals. The Court held, putting *Michigan Academy* aside for the moment, that § 405(h), as interpreted by *Salfi* and

Ringer, "would clearly bar this section 1331 lawsuit." 529 U.S. at 11, 120 S.Ct. 1084. It wrote:

> Despite the urging of the Council and supporting *amici,* we cannot distinguish *Salfi* and *Ringer* from the case before us. Those cases themselves foreclose distinctions based upon the "potential future" versus the "actual present" nature of the claim, the "general legal" versus the "fact-specific" nature of the challenge, the "collateral" versus "noncollateral" nature of the issues, or the "declaratory" versus "injunctive" nature of the relief sought. Nor can we accept a distinction that limits the scope of § 405(h) to claims for monetary benefits. Claims for money, claims for other benefits, claims for program eligibility, and claims that contest a sanction or remedy may all similarly rest upon individual fact-related circumstances, may all similarly dispute agency policy determinations, or may all similarly involve the application, interpretation, or constitutionality of interrelated regulations or statutory provisions. There is no reason to distinguish among them in terms of the language or in terms of the purposes of § 405(h). Section 1395ii's blanket incorporation of that provision into the Medicare Act as a whole certainly contains no such distinction. Nor for similar reasons can we here limit those provisions to claims that involve "amounts."

Id. at 13-14, 120 S.Ct. 1084.

The Court also explained the rationale underlying § 405(h). At the outset, it conceded that "[t]he scope of the italicized language 'to recover on any claim arising under' the Social Security (or, as incorporated through § 1395ii, the Medicare) Act, is, if read alone, uncertain." *Id.* at 10, 120 S.Ct. 1084. Nonetheless, the Court held that the meaning and import of § 405(h) are clear in light of *Salfi* and *Ringer.* It explained:

> [T]he bar of § 405(h) reaches beyond ordinary administrative law principles of "ripeness" and "exhaustion of administrative remedies"—doctrines that in any event normally require channeling a legal challenge through the agency.
>
> Insofar as § 405(h) prevents application of the "ripeness" and "exhaustion" exceptions, i.e., insofar as it demands the *"channeling" of virtually all legal attacks* through the agency, it assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts applying "ripeness" and "exhaustion" exceptions case by case. But this assurance comes at a price, namely, occasional individual, delay-related hardship. In the context of a massive, complex health and safety program such as Medicare, embodied in hundreds of pages of often interrelated regulations, any of which may become the subject of a legal challenge in any of several different courts, paying this price may seem justified. In any event, such was the

> judgment of Congress as understood in *Salfi* and *Ringer.*

Id. at 12-13, 120 S.Ct. 1084 (citations omitted) (emphasis added).

The Court then discussed whether *Michigan Academy* somehow modified *Salfi* and *Ringer.* The Court held that *Michigan Academy* did not modify *Salfi* and *Ringer* "by limiting the scope of [§] 1395ii and therefore § 405(h) to amount determinations." *Id.* at 15, 120 S.Ct. 1084 (internal quotations omitted). The Court noted that *Michigan Academy* involved a § 1331 challenge to regulations which, at the time, were not administratively or judicially reviewable. Because no administrative or judicial review of the regulations was available, the Court in *Michigan Academy* allowed the family physicians to mount a challenge directly in a court of law under § 1331. Thus, the Court in *Illinois Council* seemed to read *Michigan Academy* as creating an exception to the channeling requirement of § 405(h) in those cases where no judicial review is available at all. *Id.* at 19, 120 S.Ct. 1084 ("[I]t is more plausible to read *Michigan Academy* as *holding* that § 1395ii does not apply § 405(h) where application of § 405(h) would not simply channel review through the agency, but would mean no review at all.") (emphasis in original).[12]

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12. In *Illinois Council,* the Court noted that § 405(h) "demands the 'channeling' of virtually all legal attacks through the agency." 529 U.S. at 13, 120 S.Ct. 1084. Since *Illinois Council* limited *Michigan Academy* to those instances were there was no review available at all, we assume that the Court's use of the phrase "virtually all legal attacks" is a specific reference to *Michigan Academy.*

Our discussion of these four cases leads us back to the question of whether the district court had federal question jurisdiction over Fanning's amended class action complaint seeking to enjoin the government's attempt to obtain reimbursement of Medicare overpayments pursuant to the secondary payer provisions of the MSP. We believe that *Salfi, Ringer* and *Illinois Council* compel the conclusion that the district court had no federal question jurisdiction.

The essence of the claim asserted in Fanning's amended class action complaint is that the government is not entitled to recover Medicare overpayments from a fund created as a result of a settlement with an alleged tortfeasor because Congress never intended to treat a settlement trust fund as payments from a primary insurer under the MSP. We believe there may be force to Fanning's argument. However, the government's basis for seeking MSP reimbursement from the AcroMed settlement trust fund is that AcroMed is a "self-insured plan" and is, therefore the primary payer under the MSP. Accordingly, the claim asserted in the amended class action complaint is wholly dependent upon determining whether or not AcroMed is a "self-insured plan" and, therefore, a "primary plan" under the MSP.[13] It is thus

13. As noted, the statutory definition of "primary plan" includes plans that are self-insured. 42 U.S.C. § 1395y(b)(2) ("the term 'primary plan' means . . . a workmen's compensation law or plan, an automobile or liability policy or plan (including a self-insured plan) or no fault insurance."). Under the regulations, a "plan" is defined as "any arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness." 42 C.F.R. § 411.21. The term "self-insured plan" is defined as a "plan under which an individual, or a private or (Cont'd)

apparent that both the standing and the substantive basis for the claim asserted in the amended class action complaint are rooted in, and derived from, the Medicare Act. Consequently, the claim is one "arising under" the Medicare Act and the third sentence of § 405(h) therefore deprived the district court of federal question jurisdiction. The AcroMed class settlement plaintiffs are thus required by § 405(h), as interpreted by *Salfi, Ringer* and *Illinois Council,* to channel their claim through the agency.

Of course, the AcroMed class settlement plaintiffs would not have to channel their claim through the agency if they could avail themselves of the *Michigan Academy* exception. That is to say, channeling would not be required if they could show that they have no way of having their claims reviewed. To that end, they do claim that there is no administrative review of the agency's demand for MSP reimbursement. Therefore, they argue that a suit filed under the district court's

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(Cont'd)

governmental entity, carries its own risk instead of taking out insurance with a carrier." 42 C.F.R. § 411.50(b)(2). A "self-insured plan" includes an "entity engaged in a business, trade or profession." *Id.*

Although it has no bearing on our decision, we note that the government's argument that a "self-insured plan" includes a fund created by a tortfeasor to settle litigation has engendered a circuit split. The Fifth Circuit, in *Thompson v. Goetzmann,* 315 F.3d 457, 470 & n. 65 (5th Cir.2002), *opinion withdrawn and reissued as amended on other grounds,* 337 F.3d 489 (5th Cir.2003), rejected the government's argument, while the Eleventh Circuit, in *United States v. Baxter Intern., Inc.,* 345 F.3d 866, 2003 WL 22120071 (11th Cir. Sept.15, 2003), accepted it.

federal question jurisdiction is the only avenue available to challenge the agency's reimbursement demand.

However, the class members' assertion of no administrative review of the agency's demand for MSP reimbursement is plainly wrong. The letters sent to the approximately 1,800 settlement class members clearly advised them of the administrative process by which they could appeal the agency's determination or, in the alternative, seek a waiver of Medicare's claim for reimbursement.[14] More importantly, the Medicare Manual sets out, at length, the "procedures to be used in processing appeals of MSP liability overpayment and waiver determinations." Medicare Intermediary Manual, Part 3, § 3419.[15] Therefore, the *Michigan Academy* exception is not available to the AcroMed settlement class members.

In a further attempt to establish jurisdiction, the AcroMed class settlement members argue that § 405(h) does not apply

14. The Medicare beneficiary may ask the Secretary to waive recovery in full or in part. The Secretary may waive recovery when the beneficiary was not at fault and recovery would defeat the purposes of the Medicare Act or be against equity or good conscience. *See* 42 U.S.C. § 1395gg(c). The regulations explain that the purposes of the Medicare Act would be defeated if recovery would deprive a person of income required for ordinary and necessary living expenses, including medical expenses. *See* 42 C.F.R. § 405.358; 20 C.F.R. § 404.508(a). The Secretary's waiver determination is subject to administrative and judicial review. *See* 42 U.S.C. § 1395ff(b)(1); 42 C.F.R. §§ 405.704(b)(14), 405.720-730.

15. The pertinent Manual provisions are available at http://cms.hhs.gov/manuals/13_int/a3toc.asp.

because their complaint seeks neither a benefit determination nor a review of benefit determinations, but is instead a challenge to the right of Medicare to seek reimbursement of alleged overpayments from a trust fund created as a result of a settlement with a tortfeasor. We agree with that characterization of the class members' claim. However, under *Salfi, Ringer* and *Illinois Council,* that distinction is irrelevant. The appropriate inquiry is whether the Medicare Act provides both the standing and the substantive basis for their contentions. Clearly it does, because the dispositive issue is whether AcroMed is a "self-insured plan" within the meaning of the MSP.[16]

The AcroMed class settlement plaintiffs next argue that the agency's demand letters to them is final agency action from which they can seek judicial review. However, that argument is without merit. The demand letters, although harsh in their terms and probably unsettling to their recipients, advised the class settlement plaintiffs of their administrative review rights. Therefore, it is difficult to define them as final,

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16. Moreover, we note, but do not decide, that a reasonable argument can be made that the AcroMed class settlement members are in fact seeking benefits. As the government says: "[P]laintiffs do seek benefits: they are effectively seeking to require that Medicare make primary, rather than secondary, payment for medical expenses related to their settlement with AcroMed." Government's Br. at 25. In addition, one court of appeals has held that a Medicare beneficiary's "claim that she is entitled to the overpayment is, in essence, one for medicare benefits." *Buckner v. Heckler,* 804 F.2d 258, 260 (4th Cir.1986).

rather than initial, agency action.[17] Moreover, even if we

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17. We are not unsympathetic to the class settlement counsel's consternation over the wording of the 1800 letters the government sent out. Counsel claims that the language of the letters was intended more to terrify than to inform, and that, to the extent they may have served to inform, they succeeded only in misinforming large numbers of the class because the amounts stated in the letters were frequently erroneous. Although there has been no finding about the accuracy of the amounts the government requested in those letters, we agree that the wording of the letters was unnecessarily callous and threatening. A typical example of one of these letters read as follows:

> You must pay this amount (**$11,833.44**) within sixty (60) days of the date of this letter (by **July 9, 2001**). Please send a check or money order. . . .
>
> If you do not pay this amount by **July 9, 2001**, you will be required to pay interest from the date of this letter. Interest will be calculated at the rate of **13.75%** per annum in accordance with 42 C.F.R. 411.24(m). Interest will continue to accrue until the debt is paid, whether or not a waiver of recovery request or appeal is pending.
>
> If you do not pay this amount, the Medicare program may recover the amount from any Social Security or Railroad Retirement benefits to which you might otherwise be entitled, or the money may be recouped from payments Medicare would otherwise pay you. Also, please be aware that Medicare must refer delinquent debts to the Department of Treasury for offset against Federal payments that may be due or for other appropriate collection actions.

JA 98 (emphasis in original).

(Cont'd)

assume *arguendo* that the letter was final agency action, judicial review of that final action is available only through § 405(g). Under the Medicare Act, there is no judicial review of final agency action under the district court's federal question jurisdiction.[18] *Ringer,* 466 U.S. at 614-615, 104 S.Ct. 2013 ("The third sentence of 42 U.S.C. § 405(h), made

(Cont'd)

Although this language did inform class members, it no doubt did much more; it had to have coerced and frightened them as well. In fact, the coercive nature of this letter explains why one court referred to the government's "heavy-handed collection" tactics under the MSP. *In Re Dow Corning Corp.*, 250 B.R. 298, 336 (Bankr.E.D.Mich.2000). *See also Waters v. Farmers Texas County Mut. Ins. Co.*, 9 F.3d 397, 400-01 (5th Cir.1993) (expressing disappointment with "the government's overreaching interpretation of its authority under the [MSP].").

Although counsel for appellees here engages in some hyperbole in referring to the government's actions as "the apogee of a heavy-handed, coercive, neo-Stalinist approach," counsel's outrage over the threatening tone of the letters is not totally unjustified. *See* Appellee's Br. at 27. Although we would not go so far as to agree that these letters were "neo-Stalinist" tactics, they are more suggestive of tactics one might attribute to a less than reputable collection agency rather than to one's own government.

18. The AcroMed settlement class plaintiffs also argue that the district court had jurisdiction to review final agency action under the judicial review provision of the Administrative Procedure Act, 5 U.S.C. § 706. However, that "provision is not an independent grant of subject- matter jurisdiction." *Your Home Visiting Nurse Services, Inc. v. Shalala,* 525 U.S. 449, 457-58, 119 S.Ct. 930, 142 L.Ed.2d 919 (1999) (citing *Califano v. Sanders,* 430 U.S. 99, 97 S.Ct. 980 (1977)).

applicable to the Medicare Act by 42 U.S.C. § 1395ii, provides that § 405(g), to the exclusion of 28 U.S.C. § 1331, is the *sole avenue for judicial review* for all 'claim[s] arising under' the Medicare Act.") (emphasis added).

III. CONCLUSION

Thus, for the reasons set forth above, we find the AcroMed settlement class plaintiffs' claim that the government cannot seek MSP reimbursement from the settlement trust fund established by AcroMed is a "claim arising under" the Medicare Act. Therefore, Section 405(h) of the Social Security Act, made applicable to the Medicare Act by 42 U.S.C. § 1395ii, precluded the district court from having federal question jurisdiction over Fanning's amended class action complaint. Consequently, we will reverse the district court and remand with instruction to dismiss the amended class action complaint.

APPENDIX B — MEMORANDUM AND PRETRIAL ORDER NO. 2000 OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA DATED JUNE 29, 2001

UNITED STATES DISTRICT COURT
E.D. PENNSYLVANIA

MDL No. 1014

Civ.A. Nos. 01-1029, 97-381.

In re ORTHOPEDIC BONE SCREW PRODUCTS LIABILITY LITIGATION.

Daniel C. Fanning

v.

United States of America, et al.

Fanning, et al.

v.

AcroMed Corporation, et al. and All Actions.

MEMORANDUM AND PRETRIAL ORDER NO. 2000

BECHTLE, District Judge.

Presently before the court are plaintiff Daniel C. Fanning's motions for class certification and for preliminary

injunction and defendant the United States of America, *et al.'s* motion to dismiss the Amended Complaint in 01-cv-1029 ("*Fanning II*"); plaintiff Fanning, *et al.'s* ("Plaintiffs") motion to require distribution of the settlement proceeds in 97-cv-381 ("*Fanning I*"); the oppositions and responses thereto; and the exhibits and testimony received by the court at a consolidated hearing on the motions held on June 6, 2001. For the reasons set forth below, the motions for class certification, for preliminary injunction and for distribution of the settlement proceeds will be granted, and the motion to dismiss will be granted in part and denied in part.

I. *BACKGROUND*

In August 1994, the Judicial Panel on Multidistrict Litigation transferred all cases pending in federal trial courts against manufacturers of orthopedic bone screws, including AcroMed Corporation ("AcroMed"), to this court for pretrial purposes under 28 U.S.C. § 1407. On October 17, 1997, the court issued a Final Order and Judgment approving a limited fund class action settlement between Plaintiffs and AcroMed and certifying a settlement class. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 176 F.R.D. 158 (E.D.Pa.1997) ("*In re Bone Screw*"). Pursuant to the terms of the settlement agreement, AcroMed placed $100 million into an interest-bearing fund (the "AcroMed Settlement Fund").[1] *Id.* at 165-66.

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1. The court incorporates by reference *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 176 F.R.D. 158 (E.D.Pa.1997) which contains, *inter alia*, a description of the course of this litigation.

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In April 1997, defendant the United States of America, *et al.* (the "Government") first asserted its right to recover costs expended by its constituent agencies under the Medicare Secondary Payer statute, 42 U.S.C. § 1395y ("MSP") and the Medical Care Recovery Act, 42 U.S.C. § 2651-53 ("MCRA"). (P-5 at 3-8; United States' Statement of Interest at 1.) Today, the Government's claims continue to contribute to delay in the distribution of settlement proceeds.[2]

On March 1, 2001, Plaintiffs filed a motion to require distribution of the settlement proceeds without regard to the Government's claims in *Fanning I.* That same day, plaintiff Daniel C. Fanning brought suit against the Government in *Fanning II,* asserting that the Government had no right on account of the AcroMed settlement to recover payments previously made by any Government agency to class members and seeking to enjoin the Government from attempting such recovery from class members.[3]

2. For example, in what turned out to be a disappointing extension of cooperation by the settled parties and the claims administrator, the Government was given a complete list of class members from which to identify and quantify its claims. On numerous occasions between the summer of 1999 and the present, the Government was provided with computer databases with information concerning registered class members. (P-6 at 4-5.) Not until December 2000, however, did the Government make its first specific demand for payment to settle all of its Medicare related claims. This delay resulted from the Government having taken eight months to extract data concerning beneficiaries from its National Database, four months to filter out non-bone screw and otherwise irrelevant expenditures, and additional time to more accurately estimate its claims.

3. Fanning filed an Amended Complaint on June 22, 2001.

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On May 7, 2001, following the filing of the Complaint in *Fanning II,* the Health Care Financing Administration ("HCFA") sent letters to approximately 1,800 Medicare beneficiaries in the AcroMed Settlement Class, demanding repayment for amounts that Medicare allegedly furnished in relation to injuries that were the subject of the tort claims against AcroMed.[4] In pertinent part, the demand letters stated:

> Medicare has determined that you are required to reimburse the Medicare program [a specified sum] for amounts it paid for items or services relating to your orthopedic bone screw settlement with AcroMed Corporation. Federal law requires Medicare beneficiaries who obtain a liability recovery to repay the United States the amount the Medicare program paid for conditions related to that recovery. . . .
>
> You must pay this amount within sixty (60) days of the date of this letter (by July 9, 2001). . . . If you do not pay this amount by July 9, 2001, you will be required to pay interest from the date of this letter. Interest will be calculated at the rate of 13.75% per annum in accordance with 42 C.F.R. 411.24(m). Interest will continue to

4. It is not contested that HCFA did not provide class members with notice of the reimbursement claim prior to its demand for payment or an opportunity to demonstrate that there was no reimbursement liability because, for example, Medicare paid for services that were unrelated to any injury allegedly caused by AcroMed. (P-11 & Exs. 1-30.)

> accrue until the debt is paid, whether or not a waiver of recovery request or appeal is pending.
>
> If you do not pay this amount, the Medicare program may recover the amount from any Social Security or Railroad Retirement benefits to which you might otherwise be entitled, or the money may be recouped from payments Medicare would otherwise pay you.

(Pl.'s Mem. of Law in Opp'n to Defs.' Mot. to Dismiss and in Supp. of Pl.'s Mots. 1) to Am.Compl.; 2) for Class Cert.; 3) for Summ.J. Including Final Declaratory and Injunctive Relief and 4) for T.R.O. and/or Prelim. Inj. ("Pl.'s Opp'n") Ex. F.) In the Amended Complaint, Fanning asserts, *inter alia,* that the Government's demand, made pursuant to the MSP, is contrary to law, arbitrary and capricious, and violates the Constitutional rights of class members to procedural due process. (Am.Compl.¶¶ 24-54.)

II. *DISCUSSION*

Plaintiff Daniel C. Fanning seeks class certification and a preliminary injunction in *Fanning II,* whereas defendant the United States of America, *et al.* seeks dismissal of the Amended Complaint. In addition, plaintiff Fanning, *et al.* seeks an order requiring distribution of the settlement proceeds in *Fanning I.*

The court will first discuss the motions for class certification and for preliminary injunction. Then, the court will discuss the motion to dismiss. Finally, the court will

discuss the motion to require distribution of the settlement proceeds.

A. *Class Certification*

To certify a class, the court must first find that: 1) the class is so numerous that joinder of all members is impracticable; 2) there are questions of law or fact common to the class; 3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and 4) the representative parties will fairly and adequately protect the interests of the class. Fed.R .Civ.P. 23(a).

If the requirements of Rule 23(a) are satisfied, the parties must then establish that the suit fits within one of three categories of Rule 23(b). *In re Bone Screw,* 176 F.R.D. at 172 (citing *Weiss v. York Hosp.*, 745 F.2d 786, 807 (3d Cir.1984)). Fanning seeks certification pursuant to Rule 23(b)(2), under which "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief with respect to the class as a whole." For the reasons discussed below, the court finds that the suit fits within the requirements of Rule 23(a) and Rule 23(b)(2).

1. Numerosity

Rule 23(a)(1) permits class action treatment where "the class is so numerous that joinder of all members is impracticable." Fed.R.Civ.P. 23(a)(1). There are no specific standards regarding class size and it is not necessary for a plaintiff to allege the exact number of class members to

satisfy the numerosity requirement. *In re Bone Screw,* 176 F.R.D. at 173 (citation omitted).

To date, 1,800 class members have received demand letters from HCFA.[5] Thus, the numerosity prerequisite to class certification is satisfied. *See* H. Newberg, 1 *Newberg on Class Actions* § 3.05 at 3-25 (3d ed.1992) (stating that "in light of prevailing precedent, the difficulty inherent in joining as few as 40 class members should raise a presumption that joinder is impracticable, and the plaintiff whose class is that large or larger should meet the test of Rule 23(a)(1) on that fact alone"). The court finds that the joinder of that many individuals in various geographic areas clearly would be impracticable. Thus, Rule 23(a)(1)'s numerosity requirement is satisfied.

2. Commonality

The next prerequisite for class certification is that there be "questions of law or fact common to the class." Fed.R.Civ.P. 23(a)(2). Not every question of law or fact need be common to every member of the class: "[i]ndeed, a single common question is sufficient to satisfy Rule 23(a)(2)." *In re Bone Screw,* 176 F.R.D. at 173 (citations omitted).

Here, the common question is whether Medicare beneficiaries who obtain recovery from the settlement of tort litigation are obliged to repay the amounts that the Government paid for conditions related to that recovery under the MSP. This central issue is common to all class members.

5. The Government has expressed an intention to send additional letters.

The court finds that the existence of this common legal question satisfies the commonality requirement of Rule 23(a)(2).

3. Typicality

The third prerequisite to Rule 23(a)(3) class certification requires that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." Fed.R.Civ.P. 23(a)(3). Claims qualify as typical where "litigation of the named plaintiffs' personal claims can reasonably be expected to advance the interests of absent class members." *In re Bone Screw,* 176 F.R.D. at 175 (citation omitted). Typicality derives from a strong similarity of legal theories and is present where the class representative's claims and those of the class members arise from the same alleged course of conduct by the defendant. *In re Prudential Ins. Co. of Am. Sales Practices Litig.,* 148 F.3d 283, 311 (3d Cir.1998), *cert. denied,* 525 U.S. 1114, 119 S.Ct. 890, 142 L.Ed.2d 789 (1999).

In the proposed class before the court, the legal theory is typical of the entire class and the same Government conduct is at issue. The Government sent substantially identical letters to approximately 1,800 Medicare beneficiaries in the AcroMed Settlement Class. These letters demand repayment for amounts that Medicare allegedly furnished in relation to the injuries that were the subject of the tort claims against AcroMed. The letters contend that the MSP authorizes the Government to recover Medicare costs from the proceeds of a tort settlement. Thus, the court concludes that there is an

identity of interest of all class members and that Rule 23(a)(3)'s typicality requirement is satisfied.

4. Adequacy of Representation

Rule 23(a)'s final prerequisite is that "the representative parties will fairly and adequately protect the interests of the class." Fed.R.Civ.P. 23(a)(4). The question of adequacy of representation has two components. "First, the adequacy of representation inquiry tests the qualifications of the counsel to represent the class. Second, it serves to uncover conflicts of interest between named parties and the class they seek to represent." *In re Prudential,* 148 F.3d at 312 (citations and internal quotations omitted). The court finds that both class counsel and the named plaintiffs satisfy these tests.

With respect to class counsel, the Government does not challenge the qualifications of counsel to represent the class. (Fed. Defs.' Opp'n to Pl.'s Am.Mot. for Class Cert. at 10 n.9.) Further, the court has previously determined that plaintiffs' counsel are highly competent and experienced class action attorneys who have pursued the interests of the class vigorously. *In re Bone Screw,* 176 F.R.D. at 176.

With respect to the class representative, the Government asserts that Fanning does not adequately represent the class as he "seeks to deny" and "purports to . . . abandon all waiver and appeal rights for every putative class member who received a demand letter from HCFA." (Federal Defs.' Opp'n to Pl.'s Mot. for Class Certification at 13-14.) However, as stated at the hearing, class members' waiver rights are adequately preserved. The Government also contends that

Fanning does not adequately represent the class because Medicare's reimbursement demand against him, totaling $8.71, is "de minimus." (Federal Defs.' Opp'n to Pl.'s Am.Mot. for Class Cert. at 12.) However, as the Government recognizes, the size of a representative plaintiff's claim "is not determinative as to whether the plaintiff will fairly and adequately protect the interests of the class." *Denny v. Carey,* 73 F.R.D. 654, 657 (E.D.Pa.1977) (citations omitted). The court finds that the interest of the named plaintiff is sufficiently aligned with those of the absentees and that there are no disparate interests to impair Fanning's incentive to prosecute fully all aspects of the claim against the Government.

5. Rule 23(b)(2)

Under Rule 23(b)(2), class certification is appropriate where "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief with respect to the class as a whole." Fed.R.Civ.P. 23(b)(2).

Here, class members seek an injunction because the Government has sent virtually identical letters to Medicare beneficiaries, demanding immediate payment. The Government bases its identical action against class members upon its assertion that the MSP authorizes it to recover the costs of medical care from the proceeds of the tort litigation.

Thus, the court finds not only that Rule 23(a)'s requirements are met but also that the suit fits within the

requirements of Rule 23(b)(2). Accordingly, it will certify a class on behalf of:

> All persons who are members of the AcroMed Settlement Class (as defined in Pretrial Order 1117 entered in MDL 1014) and who, as a result of the Class Action Settlement Agreement with AcroMed Corporation, are subject to any Medicare-related claim, brought pursuant to the Medicare Secondary Payer statute, 42 U.S.C. § 1395y, or otherwise, by any of the defendants herein, except nominal defendants Robert E. Welsh, Jr. and PNC Bank, N.A., for reimbursement of the cost of medical care allegedly paid for or provided to them by any such defendant.

B. ***Preliminary Injunction***

Fanning next seeks an injunction to enjoin the Government from attempting recovery from class members for amounts Medicare allegedly furnished in relation to injuries that were the subject of the tort claims against AcroMed.

To obtain a preliminary injunction, the moving party must show both: the likelihood of irreparable harm without the relief sought; and a reasonable likelihood of ultimate success on the merits. *See Adams v. Freedom Forge Corp.*, 204 F.3d 475, 484 (3d Cir.2000) (setting forth standard for preliminary injunctive relief). The court also considers the likelihood of irreparable harm to the non-moving party and whether equitable relief will serve the public interest. *Id.*

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1. Irreparable Harm and the Public Interest

In considering whether to grant a preliminary injunction, the court first considers the likelihood of irreparable harm without the relief sought. "The irreparable harm requirement is met if a plaintiff demonstrates a significant risk that he or she will experience harm that cannot adequately be compensated after the fact by monetary damages." *Adams,* 204 F.3d at 484.

Pursuant to the demand letters, when a class member does not or cannot pay Medicare the amount the Government demands by July 9, 2001, Medicare may recover the amount from any Social Security or Railroad Retirement benefits to which the class member would otherwise be entitled. (Am.Compl.Ex. B. at 2.) The money may also be recouped from payments to the class member that Medicare would otherwise have made. *Id.* Finally, interest on the class member's debt will accrue at a rate of 13.75% until it is paid, and Medicare will refer delinquent debts to the Department of the Treasury for offset against Federal payments that may be due or for other collection actions. *Id.*

Although the loss of income alone may not necessarily constitute irreparable harm, in this case, class members would suffer far more than mere economic loss. The statutory scheme at issue in this case was enacted to benefit the aged and the disabled. Class members generally receive Medicare and Social Security benefits and cannot work because they have been disabled by spinal disorders unsuccessfully treated with spinal fixation devices. Thus, they are dependant on Medicare and Social Security to provide ongoing medical

care in addition to basic necessities.[6] Pursuant to the demand letters, Medicare may recover the amount demanded from Social Security or Railroad Retirement benefits to which the class member would otherwise be entitled, and may recoup the amount from payments that Medicare would otherwise make. No compensatory or other corrective relief at a later date will adequately redress such potential harm. Accordingly, the court finds that the Government's demands threaten to inflict far more than mere economic loss and that the class members have established the likelihood of irreparable harm.

The court next considers the likelihood of irreparable harm to the non-moving party. The Government asserts that granting an injunction would interfere with the Secretary of Health and Human Service's[7] delegated responsibilities to make decisions regarding the amounts of benefits payable on a beneficiary's behalf. (Federal Defs.' Opp'n to Pl.'s Mot. for Class Cert. at 35-36.) It also contends that the public has a strong interest in ensuring that Medicare monies are reimbursed. *Id.*

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6. The court notes that, in addition to the testimony heard from individual class members who attended the June 6, 2001 hearing, it has received numerous phone calls from class members calling to express their concerns regarding the Government's actions in this matter.

7. Medicare is administered by the Health Care Financing Administration (the "HCFA"), on behalf of the Secretary of the Department of Health and Human Services (the "Secretary"), who is ultimately responsible for the administration of Medicare. 42 U.S.C. § 1395kk(a); *Universal Health Servs. of McAllen, Inc. v. Sullivan*, 770 F.Supp. 704, 707 (D.D.C.1991), *aff'd*, 978 F.2d 745 (D.C.Cir.1992).

The court finds that the Government's asserted interests do not weigh strongly against an injunction. The Government makes no attempt to support its vague, generalized allegation of irreparable harm. Certainly, it has an interest in maintaining the integrity of the Medicare program, and it is not contested that the MSP was designed to further the public interest by facilitating the recoupment of certain Medicare expenditures for items or services that Congress has decided are more appropriately paid for by certain other persons or entities. Nonetheless, the court fails to see how enjoining the Government from demanding amounts that class members received under the AcroMed Settlement Agreement would interfere with the operation of the Medicare program.

Lastly, the court finds that the public has a significant interest in the efficient resolution of this mass tort litigation. Significant public funds have been expended by virtue of the court's administration of this litigation. Further delay in the distribution of settlement proceeds will not only cast doubt on the viability of the judicial system for efficiently resolving mass tort litigation, but also cause immediate and irreparable injury to the class. Thus, the court finds that equitable relief will serve the public interest.

2. Likelihood of Success on the Merits

The Government's assertion that it is entitled to reimbursement from the AcroMed Settlement Fund and/or from Settlement beneficiaries, for amounts that the Government paid to those beneficiaries for conditions related to their settled claims, is based on the MSP, 42 U.S.C. § 1395y.

Appendix B

The MSP consists of a series of amendments to Medicare that grant the Government a statutory right to recover certain Medicare expenditures, creating a direct cause of action in favor of the Government that is enforceable through judicial action. *In re Diet Drugs Prods. Liab. Litig.*, No. 99-20593, 2001 WL 283163, at *9 (E.D.Pa. Mar. 21, 2001) (citing *Health Ins. Ass'n of Am. v. Shalala*, 23 F.3d 412, 425 (D.C.Cir.1994)).[8] The statute makes Medicare a "secondary" payer where another entity, a "primary payer" is required to pay under a "primary plan" for an individual's healthcare. 42 U.S.C. § 1395y(b)(2); *In re Diet Drugs*, 2001 WL 283163, at *9; *United States v. Philip Morris, Inc.*, 116 F.Supp.2d 131, 145 (D.D.C.2000). If the Government, as secondary payer, makes a payment for which a primary plan is responsible, the payment is conditioned on reimbursement from the primary payer. 42 U.S.C. § 1395y(b)(2)(B)(i). The MSP grants the Government a cause of action against the primary payer, or any person who has received payment therefrom, for reimbursement of those payments or double damages.[9] *Id.* § 1395y(b)(2)(B)(ii).

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8. The court hereby incorporates by reference its reasoning *In re Diet Drugs Prods. Liab. Litig.*, No. 99-20593, 2001 WL 283163 (E.D.Pa. Mar. 21, 2001), which discusses the MSP.

9. Specifically, the MSP states that:

> [i]n order to recover payment under this subchapter for such an item or service, the United States may bring an action against any entity which is required or responsible . . . to make payment with respect to such item or service . . . under a primary plan (and may . . . collect double damages against that entity), or against any other entity

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Appendix B

The MSP defines a "primary plan" as "a group health plan or large group health plan, . . . a workman's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance . . ." under which payment for medical care "has been made or can reasonably be expected to be made promptly." 42 U.S.C. § 1395y(b)(2)(A); *In re Diet Drugs,* 2001 WL 283163, at *9. "Promptly" is defined as "payment within 120 days after receipt of the claim." 42 C.F.R. § 411.21.

The Government states that it is entitled to recover payments made to Medicare beneficiaries who are also members of the AcroMed Settlement Class because AcroMed is a "self-insurer" obligated to reimburse the Government for Medicare expenditures by the plain terms of the MSP. According to the Government, an entity that enters a liability settlement for alleged tortious conduct and funds that settlement with its own assets or borrowings is a "self-insured plan" that qualifies as a "primary plan." Further, the

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> (including any physician or provider) that has received payment from that entity with respect to the item or service, and may join or intervene in any action related to the events that gave rise to the need for the item or service. . . .

42 U.S.C. § 1395y(b)(2)(B)(ii). The MSP further provides that the Government "shall be subrogated . . . to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan." *Id.* § 1395y(b)(2)(B)(iii).

Government asserts that the situations in which the MSP makes Medicare a secondary payer entitled to reimbursement are not limited to payments for items or services for which another party has made prompt payment or can reasonably be expected to pay promptly. Lastly, the Government argues that its interpretation of the MSP is entitled to deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984).

The Government's argument fails as a matter of law because: the term "self- insurer" as used in the MSP was not meant to encompass alleged tortfeasors who merely fund liability settlements with their own assets or corporate borrowings; and the MSP makes a Government payment conditional, and thus subject to reimbursement, only where the insurance entity has made prompt payment or can reasonably be expected to make prompt payment for costs related to the federal beneficiary's medical treatment.

The court will first address whether the Government's interpretation of the MSP is entitled to deference under *Chevron,* and then address the parties' arguments regarding whether the AcroMed Settlement Trust or AcroMed itself is a "self-insured plan" qualifying as a "primary plan" obligated by the MSP to reimburse the Government.

a. *Whether Deference is Due*

As an initial matter, contrary to the Government's contention, its interpretation of the MSP is not entitled to deference under *Chevron. See Chevron,* 467 U.S. at 844-45, 104 S.Ct. 2778 (holding that court must give effect to agency *regulation* containing a reasonable interpretation of

ambiguous statute). Agency opinions that are not arrived at after a formal adjudication, notice-and-comment rulemaking, or otherwise in the exercise of congressionally delegated rulemaking authority—such as interpretations in the instant demand letters, as well as interpretations in legal briefs, opinion letters, policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant deference under *Chevron*. *See, e.g., United States v. Mead Corp.*, __ U.S. __, 121 S.Ct. 2164, 150 L.Ed.2d 292 (2001) (holding that tariff classification rulings in individual cases by United States Customs Service are not entitled to *Chevron* deference)[10]; *Christensen v. Harris County*, 529 U.S. 576, 587, 120 S.Ct. 1655, 146 L.Ed.2d 621 (2000) (holding that interpretation in opinion letter not entitled to deference) (citations omitted); *Martin v. Occupational Safety and Health Review Comm'n*, 499 U.S. 144, 157, 111 S.Ct. 1171, 113 L.Ed.2d 117 (1991) (stating that interpretative rules and enforcement guidelines are "not entitled to the same deference as norms that derive from

10. *Mead Corp.* was decided twelve days after the June 6, 2001 hearing regarding the instant motions. The parties have not submitted supplemental papers addressing the decision, and the deference issue has not been extensively briefed or argued by any of the parties.

There is no indication here that the Government's interpretation was arrived at through HCFA's congressionally delegated rulemaking authority. *See, e.g., Mead Corp.*, __ U.S. __, 121 S.Ct. 2164, 150 L.Ed.2d 292 (concluding that no deference was due to U.S. Customs Service's tariff classification rulings where there was no indication that agency "ever set out with lawmaking pretense in mind" when it made such rulings). Even if it had been and deference was due, the Government's interpretation is clearly unsupportable for the reasons discussed *infra*.

the exercise of . . . delegated lawmaking powers"); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212-213, 109 S.Ct. 468, 102 L.Ed.2d 493 (1988) (exhibiting Court's near indifference to interpretation advanced for first time in litigation brief). Rather, such interpretations are entitled to respect only to the extent that they have the power to persuade. *Mead Corp.*, __ U.S. __, 121 S.Ct. 2164, 150 L.Ed.2d 292 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140, 65 S.Ct. 161, 89 L.Ed. 124 (1944)); *Christensen*, 529 U.S. at 587, 120 S.Ct. 1655. For the reasons set forth below, the court finds the Government's interpretation of the MSP entirely unpersuasive. *See In re Dow Corning Corp.*, 250 B.R. 298, 336 n. 21 (Bankr.E.D.Mich.2000) (stating that Government's statutory construction is "entirely unsupported by the statute" and appears to be intended to convert MSP from sensible fiscal cost-cutting measure into heavy-handed collection tool).

b. *"Self-Insured Plan" Under the MSP*

The Government notes that under the Health Care Financing Administration's ("HCFA") regulations, a "'self-insured plan' . . . 'means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier.'" *See* Federal Defs.' Opp'n to Pl.'s Mot. for T.R.O. and/or Prelim. Inj. ("Opp'n to Mot. for T.R.O.") at 28 (quoting 42 C.F.R. § 411.50(b)). It further points out that a "self-insured plan" includes an "entity engaged in a business, trade or profession." *Id.* (quoting 42 C.F.R. § 411.50(b)). HCFA regulations define a "plan" as "any arrangement, oral or written, by one or more

entities, to provide health benefits or medical care or assume legal liability for injury or illness." 42 C.F.R. § 411.21.

From these provisions, the Government concludes that an entity that enters a liability insurance settlement, i.e., an arrangement in which an entity that has chosen to carry its own risk agrees to assume legal liability for injury or illness, is a self-insured plan under the MSP. (Opp'n to Mot. for T.R.O. at 29-30.) For the following reasons, however, the Government cannot establish that AcroMed or the AcroMed Settlement Fund are "self-insured plans" as defined by the MSP.

First, the HCFA itself, the entity charged with administering Medicare and that promulgated the regulations to which the Government cites, has indicated that:

> the mere absence of insurance purchased from a carrier does not necessarily constitute a 'plan' of self-insurance. If . . . the absence of insurance purchased from a carrier does not constitute a 'self-insured plan' in a particular case, HCFA will not attempt to recover its payments from the entity that lacks insurance coverage.

54 Fed.Reg. 41727 (Oct. 11, 1989) (responding to comment that regulations should clarify whether Medicare is primary payer when presumed tortfeasor has no liability insurance). Thus, the scope of entities that fall within the definition of a "self-insured plan" clearly does not encompass all entities that make payments, independent of any liability insurance

coverage, potentially related to conditions for which Medicare has made payment.

Second, there is simply no basis to conclude that Congress intended the MSP to create in the Government a right to recover from alleged tortfeasors for injuries resulting in Medicare payments. *In re Diet Drugs,* 2001 WL 283163, at. Unlike the MCRA, the MSP does not mention a right by the Government to recover from a tortfeasor. *Id.* Rather, the express wording of the statute creates a cause of action only against insurers and their payees. *Id.; see United States v. Rhode Island Insurers' Insolvency Fund,* 80 F.3d 616, 622 n.5 (1st Cir.1996) (stating that MSP "limits reimbursement to recoveries from 'primary plans,' whose definition lists only entities which are clearly 'within' the insurance industry"); *Philip Morris, Inc.,* 116 F.Supp.2d at 146 & n.22 (dismissing MSP claim against defendants who clearly were not insurance entities and noting that courts have uniformly recognized that statute's clear purpose was to grant Government right to recover Medicare costs from insurers) (citations omitted); *Dow Corning,* 250 B.R. at 337 n.22 (stating that unless alleged tortfeasor qualifies as primary plan or received payment from primary plan, MSP does not grant right to initiate direct action against it); *see also Health Ins. Ass'n,* 23 F.3d at 427 n.* (stating that MSP "plainly intends to allow recovery only from an insurer") (Henderson, J., concurring). Under the Government's construction of the statute, every tortfeasor that used its general assets to fund a tort settlement with persons who had received federal health care benefits would be potentially liable under the MSP. *In re Diet Drugs,* 2001 WL 283163, at *10. There is absolutely no legal support for this extremely broad construction of the statute. *Id.* The

court's conclusion is bolstered by the fact that up until the recent *Philip Morris* and *Dow Corning* cases, the case law is devoid of any instances in which the Government attempted to sue a tortfeasor under the MSP, despite the fact that the statute had been in existence for twenty years. *Philip Morris,* 116 F.Supp.2d at 146 n. 22. As noted by this court in *In re Diet Drugs* and by Judge Kessler in *Philip Morris,* " 'it is clear that Congress did not intend MSP to be used as an across the board procedural vehicle for suing tortfeasors.' " *In re Diet Drugs,* 2001 WL 283163, at *10 (quoting *Philip Morris,* 116 F.Supp.2d at 135).

Lastly, the Government asserts that HCFA's regulation in 42 C.F.R. § 411-50(b) clarifies that the Government has an MSP claim with respect to monies paid by a tortfeasor. That provision states in relevant part that a "[l]iability insurance payment" subject to the MSP "means a payment by a liability insurer, or an out-of-pocket payment, including a payment to cover a deductible required by a liability insurance policy, by an individual or other entity that carries liability insurance, or is covered by a self-insured plan." 42 C.F.R. § 411.50(b). The Government's argument, however, fails to account for the repeated use of the word "plan" throughout the MSP and regulations promulgated thereunder, including the regulation it cites. *See* 42 C.F.R. § 411.50(b) (defining self-insured plan as "plan" under which entity carries its own risk, including "plan" of business entity).

The plain meaning of the term "self-insured plan" and the statutory context in which that term is used indicate that it does not include tortfeasors that merely have the ability to, and do in fact, fund a settlement of a tort suit with general

assets of the company or corporate borrowings. *In re Diet Drugs,* 2001 WL 283163, at *10. The statute's requirement of the existence of a primary "plan" connotes some type of formal arrangement by which an entity consciously undertakes to set aside funds to cover potential future liabilities and a formal procedure for processing claims made against that fund pursuant to the terms of the "plan." *In re Diet Drugs,* 2001 WL 283163, at *10; *see Moore v. Warehouse Club, Inc.*, 992 F.2d 27, 29 (3d Cir.1993) (stating that, as a matter of statutory construction, words "will be interpreted as taking their ordinary, contemporary, common meaning"). For example, a leading treatise on the subject of insurance states that:

> . . . to meet the conceptual definition of self-insurance, an entity would have to engage in the same sorts of underwriting procedures that insurance companies employ; estimating likely losses during the period, setting up a mechanism for creating sufficient reserves to meet those losses as they occur, and, usually, arranging for commercial insurance for losses in excess of some stated amount.

1 Couch on Insurance 10:1 (citing, as an example, IBM's historical self- insurance of employee health benefits); *see Alderson v. Ins. Co. of N. Am.*, 223 Cal.App.3d 397, 407, 273 Cal.Rptr. 7 (1990) (noting that it is implicit in term "self-insurer" that such entity maintains reserve, to cover possible losses, from which it pays out valid claims and that self-insurer has procedure for considering such claims and managing reserve); *see also In re Diet Drugs,* 2001 WL

283163, at *10-11 (concluding that settlement trust funded by alleged tortfeasor's own funds does not constitute "self-insured plan" for purposes of MSP) (citations omitted); *Dow Corning*, 250 B.R. at 339 (stating that "[w]e are dubious that the term 'self-insured plan' covers or was meant to cover every tortfeasor who fails to obtain insurance") (citations omitted). HCFA's definitions of a "self-insurer" and a "plan" are not to the contrary. 42 C.F.R. §§ 411.21 & 411.50(b). Thus, it is doubtful that the Government can maintain a cause of action against AcroMed, the AcroMed Settlement Fund or class members simply by virtue of the fact that AcroMed funded the Settlement with its own funds or corporate borrowings rather than those of a liability insurer. Furthermore, the Government has proffered no evidence, and has not even alleged, that AcroMed maintains such a formal plan of self-insurance in order to cover possible losses.

Given the plain language of the MSP, its legislative history, the case law interpreting it and the absence of any reported decision in which the Government has prevailed under MSP against an entity that was clearly outside of the insurance industry, the court concludes that the Government's MSP cause of action arises when the "primary plan" is obligated to pay for the primary care at issue under a contract of insurance or other formal insurer-insured relationship, not when the payment obligation arises out of tort litigation.[11]

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11. When pursuing MSP reimbursement in the context of a formal plan of self-insurance, the Government could point to the terms of the plan to support its demand for reimbursement, regardless of whether or not the federal beneficiary made a claim against the plan. However, in the context of an alleged tortfeasor, if the

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See In re Diet Drugs, 2001 WL 283163, at *11 (agreeing that double penalties might be appropriate against insurer who fails to honor contractual obligation to pay, but not against tortfeasor). To read the statute otherwise would lead to the conclusion that Congress authorized double damages against alleged tortfeasors merely for contesting liability.[12] *Id.* When the full history of the instant topic is considered, it becomes eminently clear that Congress could not have intended, and indeed did not intend, such a result. *See id.* (reaching identical conclusion).

c. *MSP's "Prompt Payment" Requirement*

Even if the AcroMed Settlement Trust fell within the general meaning of a "self-insured plan," it does not qualify as a "primary plan" obligated by the MSP to reimburse the Government for Medicare expenditures because it is not a "self-insured plan" under which payment for medical care

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Government's interpretation of the MSP was correct, its right to seek reimbursement would presumably be contingent on whether the federal beneficiary filed suit and prevailed against or settled with that tortfeasor. The court finds it bizarre and unlikely that Congress could have intended that the Government's right of recovery would be contingent on the federal beneficiary's decision of whether to seek reimbursement and the additional contingency of a judgment or settlement involving money for injuries for which the plaintiff received Medicare payments.

12. In entering the Settlement Agreement, AcroMed did not admit or concede liability and the Agreement expressly states that it shall not be construed as an admission or concession of liability. (P-1 at § II.C.)

"has been made or can reasonably be expected to be made promptly." 42 U.S.C. § 1395y(b)(2)(A).

As already explained by this court's opinion in *In re Diet Drugs* and the exhaustively thorough and well reasoned opinion in *Dow Corning*, § 1395y(b)(2)(A) of the MSP defines a "primary plan" as including a liability insurance policy or plan, including a self-insured plan, "to the extent that" payment for health care "can reasonably be expected to be made promptly" under that policy. *See* 42 U.S.C. § 1395y(b)(2)(A) (stating that "primary plan" means "liability insurance policy . . . to the extent that" § 1395y(b)(2)(A)(ii), encompassing plans that can reasonably be expected to make prompt payment, applies); *In re Diet Drugs*, 2001 WL 283163, at *11 n.20 (concluding that MSP applies to "primary plan" under which payment for medical care "has been made or can reasonably be expected to be made promptly"); *Dow Corning*, 250 B.R. at 348 n. 29 (same). Thus, if a liability insurance policy has not made prompt payment and cannot reasonably be expected to pay promptly for the health care at issue, it is not a "primary plan." *In re Diet Drugs*, 2001 WL 283163, at *11 n.20 (citing *Dow Corning*, 250 B.R. at 348 n.29 and *Health Ins. Ass'n*, 23 F.3d at 419).

Under the MSP, a Medicare payment is only conditional, and the Government only becomes a "secondary payer," if that payment is for an item or service to which § 1395y(b)(2)(A) applies. 42 U.S.C. § 1395y(b)(2)(B)(i). Therefore, when Medicare pays for health care to which § 1395y(b)(2)(A) does not apply—for example, payment for an item or service that the Government cannot reasonably expect to be paid for promptly under the terms of the

insurance plan—the Medicare payment is not conditional and the Government does not acquire secondary payer status with respect to that payment or the corresponding authority to initiate a recovery action under § 1395y(b)(2)(B)(ii).[13] *In re Diet Drugs*, 2001 WL 283163, at *11 n.20; *Dow Corning*, 250 B.R. at 346 n.29.

HCFA regulations state that a payment is made "promptly" if made within 120 days after the earlier of the date the care was provided or the date a claim is filed with the insurer. 42 C.F.R. §§ 411.21, 411.50. Given the time delay inherent in strongly prosecuted and defended tort litigation, the Government cannot legitimately assert that a settlement arrived at in the heat of a hard fought adversarial engagement for alleged tort liability from a defective product is the type of insurance "plan" that the Government can reasonably expect to make prompt payment for medical care.[14] *In re Diet*

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13. For these reasons, the statement in *Philip Morris* that "[i]f the 'primary' payer has an obligation to pay for such costs, but does not and cannot 'reasonably be expected' to do so, Medicare may make a 'conditional payment' and later demand reimbursement from the primary plan" is too broad. *Philip Morris*, 116 F.Supp.2d at 145. It is the obligation to make prompt payment "under" the plan that makes an entity a "primary" payer and the Government the "secondary" payer. *In re Diet Drugs*, 2001 WL 283163, at *11 n.20. The court notes, as it did in *In re Diet Drugs*, that this issue was not germane to Judge Kessler's otherwise thorough and well-reasoned decision. *Id.*

14. It should be noted that the other types of insurance included in the definition of a "primary payer" under § 1395y(b)(2)(A), i.e., workmen's compensation, automobile and no fault insurance, are

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Drugs, 2001 WL 283163, at *11 n. 20; *see, e.g., Evanston v. Hauck*, 1 F.3d 540, 544 (7th Cir.1993) (stating that tort judgment "can in no sense be considered the kind of certain, prompt third-party payment Congress had in mind when it wrote the Medicare statute"); *Dow Corning*, 250 B.R. at 348 n. 29 (noting that it would seem folly for Government to argue that when it made Medicare payments on behalf of breast implant recipients, there was reasonable expectation that third-party would promptly pay for such care). Further, because the AcroMed Settlement was not even in existence at the time that the Government made the payments at issue, it is clearly not a "plan" that was required to make "prompt" payment, i.e., payment within 120 days, for the relevant medical expenses. 42 U.S.C. § 1395y(b)(2)(A); 42 C.F.R. §§ 411.21, 411.50.

Despite the explicit terms of the MSP, the case law interpreting it and the complete inability to cite any contrary authority on point, the Government contends that the foregoing interpretation of the MSP "turns the statute on its head by limiting HCFA's right to reimbursement to situations in which payment is expected to be made promptly." However, as noted above, § 1395y(b)(2)(B)(i) limits the Government's reimbursement remedy to any payment falling under § 1395y(b)(2)(A), which applies only to payments with respect to an item or service to the extent that payment has been or can reasonably be expected to be made promptly

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frequently required by the terms of the policy itself to make prompt payment for medical expenses. *See, e.g.*, 47 Fed.Reg. 21103 (stating that "under automobile medical or no fault insurance, payment can frequently be foreseen with reasonable certainty").

under a self-insured plan. Thus, the statute by its terms limits the Government's right to reimbursement to situations in which prompt payment has been made or can reasonably be expected by a "primary plan." Any other interpretation flies in the face of the MSP's explicit terms.

The Government's contention that Fanning's interpretation "would give the United States a right to recover only conditional payments that it is not permitted to make in the first place" is wrong. At 42 U.S.C. § 1395y(b)(2)(A), the MSP prohibits the Government from making payments "*except as provided in subparagraph (B)*" to the extent that another entity is reasonably expected to pay promptly for such items or services. (Emphasis added.) Subparagraph (B) then provides that the Government's payment is conditional when it makes a payment for items or services for which another entity is reasonably expected to pay promptly. 42 U.S.C. § 1395y(b)(2)(B)(i) (making payment covered by § 1395y(b)(2)(A) conditional). Thus, the statute expressly permits the Government to make payment for items or services for which another entity is required to pay promptly, but makes such payments subject to the Government's right to reimbursement through the cause of action created in § 1395y(b)(2)(B)(i).

This interpretation is entirely consistent with the court's conclusion that the Government's MSP cause of action arises when the "primary plan" is obligated to pay for the primary care at issue under a contract or other formal plan of insurance, not when the payment obligation arises out of tort litigation. Given this logical definition of a "primary plan," the Government's argument that the court's interpretation

would allow any liability insurance policy or plan to "escape liability entirely by disputing a claim or otherwise failing to make payments in a prompt fashion" is clearly without merit. If it was later determined that the terms of the policy or plan obligated the relevant entity to make prompt payment for medical care related to the conditions at issue, then that entity is one that could reasonably have been expected to make prompt payment, entitling the Government to reimbursement should it make a conditional payment. Whether or not the insuring entity contested liability would be irrelevant to whether it was obligated, and therefore was reasonably expected, to make prompt payment under the terms of the plan, and the Government's right to initiate suit for reimbursement "when notice ... is received that payment for such item or service has been ... made" would remain intact. 42 U.S.C. § 1395y(b)(2)(B)(i). Thus, contrary to the Government's contention, the court's interpretation in no way minimizes a private insurer's financial obligation to its insured. *See* Opp'n to Pls.' Mot. For T.R.O. at 31 (citing *United States v. Geier,* 816 F.Supp. 1332, 1336 (W.D.Wis.1993), which indicates that Congress did not intend MSP to minimize insurer's obligation to insured).

Lastly, if the court were to accept the Government's interpretation of the MSP, as discussed above, all entities possessing or borrowing sufficient funds to cover tort liabilities would be liable for double damages if they entered a settlement or received an adverse judgment more than 120 days after the suit was filed or a claim was otherwise formally prosecuted. *See* 42 U.S.C. § 1395y(b)(2)(B)(ii) (permitting Government to sue for double damages against entity that is required or responsible to pay for item or service

covered by MSP). Obviously, this situation presents itself in the overwhelming majority of tort lawsuits. It is implausible that Congress intended such a result, and even if it had, the court doubts whether the MSP's application in this manner would withstand constitutional scrutiny. The Government fails to address this flaw in its interpretation.

Thus, even if AcroMed or the AcroMed Settlement Fund fall within the definition of "self-insured plan" under the MSP, neither is a "primary payer" against which the Government can seek reimbursement because neither could reasonably be expected to make prompt payment for medical costs. 42 U.S.C. § 1395y(b)(2)(A).

For all of these reasons, the court concludes that the class members have demonstrated that they are likely to ultimately prevail on the merits of the Government's MSP claim.

Appendix B

C. *Motion to Dismiss*[15]

In its motion to dismiss, the Government first argues that the court must dismiss the Amended Complaint because the Medicare Act precludes jurisdiction and because the Government has not waived sovereign immunity. The Government next argues that the claims against those federal defendants who are not alleged to have taken any action against the class members must be dismissed.

As stated below, the court finds that the Medicare statutory scheme does not preclude judicial review in this case and that government immunity is waived under the Administrative Procedures Act, 5 U.S.C. § 702 *et seq.* ("APA"). Thus, the court has jurisdiction under 28 U.S.C. § 1331 (federal question) and will not dismiss the Amended Complaint for lack of jurisdiction. However, the court will grant the motion to dismiss insofar as the Amended Complaint fails to allege any action by certain federal

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15. For the purposes of a motion to dismiss, the court must accept as true all well-pleaded allegations of fact in a plaintiff's complaint, construe the complaint in the light most favorable to the plaintiff, and determine whether "under any reasonable reading of the pleadings, the plaintiff may be entitled to relief." *Colburn v. Upper Darby Township,* 838 F.2d 663, 665-66 (3d Cir.1988). The court, however, need not accept as true legal conclusions or unwarranted factual inferences. *Morse v. Lower Merion Sch. Dist.,* 132 F.3d 902, 906 (3d Cir.1997) (citations omitted). A complaint is properly dismissed only if "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson,* 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957).

defendants who are not alleged to have taken any action against the class members.

1. Jurisdiction

The Government first argues that the court lacks jurisdiction because 42 U.S.C. § 405(g) and (h), as incorporated by 42 U.S.C. § 1395ii, bar federal question jurisdiction where the class members have not exhausted their administrative remedies by pursuing administrative appeals under Section 405 of the Social Security Act.[16] Fanning,

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16. Section 405 "spells out the procedures under which applications for social security benefits are adjudicated." *Ohio Hospital Ass'n v. Shalala*, 201 F.3d 418, 422 (6th Cir.1999). Under 42 U.S.C § 405(b), the Commissioner of Social Security is directed to make findings of fact and decisions as to the rights of any individuals applying for Social Security Benefits. Upon request, the Commissioner must afford a dissatisfied applicant an evidentiary hearing. *Id.* Once the Commissioner has issued a final decision after a hearing to which the individual was a party, § 405(g) provides that the individual "may obtain review of such decision by a civil action" commenced in a United States District Court. In this statutory setting, § 405(h) provides:

> The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal or governmental agency except as therein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

however, contends that Congress did not channel review of the instant claim through 42 U.S.C. § 405(g) and (h).

The inquiry in determining whether federal question jurisdiction is barred is whether the plaintiff seeks "to recover on any claim arising under" the Medicare Act. 42 U.S.C. § 405(h); *Heckler v. Ringer,* 466 U.S. 602, 636, 104 S.Ct. 2013, 80 L.Ed.2d 622 (1984) (citing *Weinberger v. Salfi,* 422 U.S. 749, 760-61, 95 S.Ct. 2457, 45 L.Ed.2d 522 (1975)).

Here, plaintiffs do not seek "to recover" anything. They do not seek Medicare benefits or reimbursement for Medicare benefits. Nor may their claim be construed as a claim for benefits "in essence." *Ringer,* 466 U.S. at 623, 104 S.Ct. 2013. In this case, class members received benefits allegedly furnished by Medicare in relation to allegedly AcroMed-related injuries years ago. Rather than seeking "to recover on any claim arising under" the Medicare Act, class members seek an injunction to prevent the Government from undertaking action against them to obtain money that class members received or may receive under the terms of the Settlement Agreement with AcroMed.

Further, in support of its assertion that the court lacks jurisdiction because the class members failed to exhaust administrative remedies, the Government cites only cases wherein plaintiffs sought to receive Medicare benefits either immediately or in the future, *Weinberger,* 422 U.S. 749, 95 S.Ct. 2457, 45 L.Ed.2d 522, *Ringer,* 466 U.S. 602, 104 S.Ct. 2013, 80 L.Ed.2d 622, and cases concerning medical providers' eligibility for reimbursement, *Shalala v. Illinois Council on Long Term Care, Inc.,* 529 U.S. 1, 120 S.Ct. 1084,

146 L.Ed.2d 1 (2000). (Opp'n to Mot. for T.R.O. at 12-14; Govt.'s Mem. of Law in Supp. of Mot. to Dismiss Am.Compl. at 17-20.) None of these situations exist in the instant dispute. Thus, the court finds that there is simply no basis from which it may conclude that the class members' challenge to the validity and constitutionality of HCFA's demand for payment should be channeled first into the administrative process Congress provided for determination of claims for benefits.[17]

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17. Arguing that this is a case of overpayment of benefits, the Government cites *Buckner v. Heckler,* 804 F.2d 258 (4th Cir.1986), for the proposition that class members must exhaust administrative remedies before seeking relief in federal court. (Opp'n to Mot. for T.R.O. at 15 & 17.) That case, however, is inapposite. In *Buckner,* the plaintiff sued the Secretary seeking to recover an overpayment of medical benefits that resulted when both plaintiff's automobile insurer and the medicare program paid plaintiff's hospital expenses. *Id.* at 259. Buckner was admitted to the hospital following an automobile accident on December 6, 1982, incurring $20,845.45 in medical expenses. *Id.* Medicare paid $20,636.66. *Id.* Then, on February 26, 1983, eighty-two days after the hospitalization, the plaintiff's automobile insurer paid $5,317.76. *Id.* Thus, the hospital received an overpayment of $5,108.97. *Id.* Buckner filed suit against the Secretary, arguing that she was entitled to the overpayment.

Unlike *Buckner,* no medical provider in the instant case was paid twice or received an overpayment for benefits provided. In *Buckner,* prompt payment, i.e., within 120 days, was made, and was "reasonably . . . expected to be made" by the plaintiff's automobile insurance plan. 42 U.S.C. § 1395y(b)(2); *Buckner,* 804 F.2d at 259 & n. 3 (citing MSP). Because Buckner's automobile insurance was reasonably expected to make prompt payment, Medicare's payment was conditional under the MSP. *Id.* In the instant case, there was no primary plan reasonably expected to make prompt payment, thus

(Cont'd)

Appendix B

The court concludes that the Medicare statutory scheme does not preclude judicial review of the class members' claims.

Further, sovereign immunity does not apply. Judicial review to class members "suffering legal wrong[s] because of agency action, or adversely affected or aggrieved by agency action" is provided by the Administrative Procedures Act, 5 U.S.C. § 702 *et seq.* ("APA"). The APA authorizes judicial review of the actions of federal administrative agencies. The APA waives government immunity for: final agency actions; for which there is no adequate remedy at law; and for relief other than money damages.

"Final" agency actions are those that impose an obligation, deny a right, or fix a legal relationship. *Hindes v. FDIC,* 137 F.3d 148, 162 (3d Cir.1998) (citing *Shea v. Office of Thrift Supervision,* 934 F.2d 41, 44 (3d Cir.1991)). To be "final," an decision must: 1) represent the agency's definitive position on the question; 2) have the status of law with the expectation of immediate compliance; 3) have an immediate impact on Plaintiffs' day-to-day operations; 4) involve a pure question of law; and 5) immediate review would speed enforcement. *Matter of Seidman,* 37 F.3d 911, 923 (3d Cir.1994) (citing *CEC Energy Co., Inc. v. Public Serv. Comm.,* 891 F.2d 1107, 1110 (3d Cir.1989)).

(Cont'd)

Medicare's payment was not conditional. Finally, unlike *Buckner,* class members do not seek the payment of benefits. Rather, they seek to enjoin the Government from attempting to recover from class members payments previously made by Medicare on account of the AcroMed settlement.

Here, HCFA's demand letters represent the agency's definitive position that under its interpretation of the MSP, the Government is entitled to reimbursement for medical expenses because of the AcroMed Settlement. The demand letters impose an obligation with the expectation of immediate compliance by July 9, 2001, or interest will accrue at a rate of 13.75%. The impact of the Government's demand is immediate, as evidenced by testimony at the hearing and the phone calls from class members the court received in chambers, and the issue involves a pure question of law. Thus, the court finds that the agency action is clearly "final" under the APA.

The court also concludes, as discussed *supra,* that there is no adequate remedy at law. Although the Government asserts that Medicare beneficiaries must exhaust administrative appeals procedures or seek waivers, it cites only regulations regarding the overpayment of benefits to medical providers and to regulations regarding conditional payments, which are not applicable for the reasons already discussed. Finally, Fanning seeks relief other than money damages, namely, an injunction. Thus, the court concludes that judicial review is authorized by the Administrative Procedures Act.

2. Defendants Not Alleged to Have Taken Action Against Class Members

In its motion to dismiss, the Government also seeks to dismiss the Amended Complaint's MCRA claims. As stated *supra,* the demand letters base the Government's demand for reimbursement entirely on the MSP. (Am.Compl.Ex.B.)

Appendix B

The Government acknowledged at the June 6, 2001 hearing that it has not sought to justify its demands for reimbursement from class members under the MCRA, which grants the Government a right to recover from tortfeasors, but does not provide a cause of action to recover Medicare expenses or allow the Government to collect from an injured person or from a settlement fund negotiated between the injured person and the settling defendant. 42 U.S.C. § 2651(a); *In re Diet Drugs,* 2001 WL 283163, at *8 (citations omitted). Thus, insofar as the Amended Complaint asserts a claim under the MCRA, the court will grant the Government's motion to dismiss said claim.

In this regard, twelve of the seventeen named defendants do not have any relationship to the MSP or the Medicare program, including: the United States Department of Defense; the United States Department of the Army; the United States Department of the Navy; the United States Department of the Air Force; the United States Indian Health Service; the United States Department of Veterans Affairs; Donald H. Rumsfeld, in his capacity as Secretary of the United States Department of Defense; Joseph W. Westphal, in his capacity as Acting Secretary of the United States Department of the Army; Robert B. Pirie, Jr., in his capacity as Acting Secretary of the United States Department of the Navy; Lawrence Delaney, in his capacity as Acting Secretary of the United States Department of the Air Force; Michael H. Trujillo, in his capacity as Director of the United States Indian Health Service; and Anthony J. Principi, in his capacity as the Secretary of the United States Department of Veterans Affairs. Thus, the court will grant the Government's motion to dismiss class member's claims against these defendants.

Accordingly, for purposes of this Memorandum and Order, the remaining "Federal Defendants" include: 1) the United States of America ("United States"); 2) the United States Health Care Financing Administration ("HCFA"); 3) the United States Department of Health and Human Services; 4) Tommy G. Thompson, in his capacity as Secretary of the United States Department of Health and Human Services; and 5) Thomas Scully, in his capacity as Administrator of HCFA, an Agency of the Department of Health and Human Services.

D. *Distribution of the Settlement Proceeds*

As to Plaintiffs' motion in *Fanning I* to require distribution of the settlement proceeds without regard to the Government's interest, the court notes that the Government expressed no objection to distribution. Further, although AcroMed initially objected in a filing dated March 27, 2001, during the June 6, 2001 hearing on the matter, AcroMed voiced no objection to distributing the settlement proceeds.[18]

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18. In its earlier objection, AcroMed asserted that the Government's claim is subrogatory in nature, and that therefore, pursuant to the settlement, AcroMed is entitled to indemnification from the Settlement Fund for any Government claims against it.

The Government, however, has raised no claim against AcroMed. Further, although the Government's claim may be subrogatory in nature, it is, nonetheless, independent. It was not extinguished by the Settlement Agreement, to which the Government was not a party. *In re Bone Screw,* 176 F.R.D. at 179 (citations omitted). Thus, the Government's claim is not a "settled claim" under Pretrial Order Number 1117. *Id.;* Settlement Agreement § IV.D.3.b (stating that AcroMed is entitled to indemnification for "settled claims").

Nevertheless, out of an exercise of extreme caution, the court will direct a reserve of $1,000,000.00 to be set-aside. The court concludes that this sum will adequately protect any interest in the settlement proceeds that the Government may ultimately establish.

III. *CONCLUSION*

For the reasons set forth above, the motions for class certification and for a preliminary injunction will be granted; the Government's motion to dismiss will be granted in part and denied in part; and the motion to require distribution of the settlement proceeds will be granted.

An appropriate Order follows.

Appendix B

ORDER

AND NOW, TO WIT, this 29 day of June, 2001, upon consideration of plaintiff Daniel C. Fanning's ("Fanning") motions for class certification and for a preliminary injunction in 01-cv-1029; defendant the United States of America, *et al.'s* motion to dismiss the Amended Complaint in 01-cv-1029; plaintiff Fanning, *et al.'s* ("Plaintiffs") motion to require distribution of the settlement proceeds in 97-cv-381; the oppositions and responses thereto; and the exhibits and testimony received by the court at a consolidated hearing on the motions held on June 6, 2001, IT IS ORDERED that:

1) Fanning's motion for class certification in 01-cv-1029 is GRANTED. Civil Action No. 01-1029 shall proceed as a class action pursuant to Fed.R.Civ.P. 23(a) and 23(b)(2) for declaratory and injunctive relief under the Administrative Procedures Act, 5 U.S.C. § 702, on behalf of a class consisting of:

> All persons who are members of the AcroMed Settlement Class (as defined in Pretrial Order 1117 entered in MDL 1014) and who, as a result of the Class Action Settlement Agreement with AcroMed Corporation, are subject to any Medicare-related claim, brought pursuant to the Medicare Secondary Payer statute, 42 U.S.C. § 1395y, or otherwise, by any of the defendants herein, except nominal defendants Robert E. Welsh, Jr. and PNC Bank, N.A., for reimbursement of the cost of medical care allegedly paid for or provided to them by any such defendant;

2) Plaintiff's Motion for a Preliminary Injunction in 01-cv-1029 is GRANTED;

3) Defendant the United States of America, *et al.'s* motion to dismiss the Amended Complaint in 01-cv-1029 is GRANTED IN PART and DENIED IN PART;

4) Until further Order of the court, the Federal Defendants[1] are hereby RESTRAINED and ENJOINED from undertaking any action to obtain reimbursement from class members in relation to any money, sums, payments or benefits that class members have received in the past or may receive in the future pursuant to the terms of the AcroMed Settlement Agreement;

5) The Federal Defendants are directed to deposit into the registry of the court any sum that has been paid in the past or which may be paid in the future to any of the Federal Defendants by or on behalf of any class member pursuant to any demand by any Federal Defendant for reimbursement in relation to the AcroMed Settlement. Such deposits shall be made within fifteen (15) days of the date of this Order or within fifteen (15) days of receipt of such payment, whichever is earlier;

---

1. For purposes of this Order, the "Federal Defendants" are: the United States of America ("United States"); the United States Health Care Financing Administration ("HCFA"); the United States Department of Health and Human Services; Tommy G. Thompson, in his capacity as Secretary of the United States Department of Health and Human Services; and Thomas Scully, in his capacity as Administrator of HCFA, an Agency of the Department of Health and Human Services.

6) In lieu of posting security, Robert E. Welsh, Jr., in his capacity as Administrator of the AcroMed Settlement Fund, and PNC Bank, N.A., in its capacity as Trustee for the AcroMed Settlement Agreement are hereby directed to hold the sum of $ 2,500.00 (two thousand five hundred dollars) out of the proceeds of the AcroMed Settlement Fund in escrow pending further Order of the court;

7) The Plaintiffs' Litigation Committee is hereby directed to send a copy of this Order and an explanatory letter to class members;

8) A final hearing on permanent injunctive relief shall be set at a future date;

9) The Federal Defendants' Motion to Stay Proceedings Related to Plaintiff's Motion for Summary Judgment or, in the Alternative, for Enlargement of Time to Respond to Plaintiff's Motion in 01-cv-1029 is DENIED AS MOOT;

10) Robert E. Welsh, Jr., in his capacity as Administrator of the AcroMed Settlement Fund, and PNC Bank, N.A., in its capacity as Trustee for the AcroMed Settlement Agreement shall establish and maintain a separate account in the amount of $1,000,000.00 (one million dollars). This reserve may be utilized, pursuant to court order, in the event that the Federal Defendants ultimately establish an interest in Settlement proceeds;

11) The Settlement Administrator and the Settlement Trust shall forthwith commence distribution of the remaining proceeds of Settlement to eligible class members in

accordance with this court's Pretrial Orders and the terms of the Settlement Agreement approved by the court in Pretrial Order No. 1117; and

12) To the extent that plaintiff Fanning seeks additional declaratory or injunctive relief, said motions are DENIED WITHOUT PREJUDICE.

SO ORDERED.

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT DENYING PETITION FOR REHEARING EN BANC DATED DECEMBER 16, 2003

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No: 01-3366

DANIEL C. FANNING, INDIVIDUALLY, AND AS REPRESENTATIVE OF A CLASS OF PERSONS SIMILARLY SITUATED

v.

THE UNITED STATES OF AMERICA; UNITED STATES HEALTH CARE FINANCING ADMINISTRATION; UNITED STATES DEPARTMENT OF DEFENSE; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF THE ARMY; UNITED STATES DEPARTMENT OF THE NAVY; UNITED STATES DEPARTMENT OF THE AIR FORCE; UNITED STATES INDIAN HEALTH SERVICE; UNITED STATES DEPARTMENT OF VETERANS AFFAIRS; MICHAEL MCMULLEN, MRS., AS ACTING DEPUTY ADMINISTRATOR OF THE UNITED STATES HEALTH CARE FINANCING ADMINISTRATION; DONALD H. RUMSFELD, AS SECRETARY OF DEFENSE; TOMMY G. THOMPSON, AS SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES; GREGORY R. DAHLBERG, THE HONORABLE, AS ACTING SECRETARY OF THE ARMY; ROBERT B. PIRIE, JR., THE HONORABLE, AS ACTING SECRETARY OF THE NAVY;

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LAWRENCE DELANEY, THE HONORABLE DR., AS SECRETARY OF THE AIR FORCE; MICHAEL H. TRUJILLO, M.D., M.P.H., AS DIRECTOR OF THE INDIAN HEALTH SERVICE; ANTHONY J. PRINCIPI, THE HONORABLE, AS SECRETARY OF THE DEPARTMENT OF VETERANS AFFAIRS; ROBERT E. WELSH, JR., ESQUIRE, AS ADMINISTRATOR OF THE ACROMED SETTLEMENT AGREEMENT; PNC BANK, N.A., AS TRUSTEE FOR THE ACROMED SETTLEMENT AGREEMENT

United States of America, the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), the United States Department of Health and Human Services, Tommy G. Thompson in his capacity as Secretary of the United States Department of Health and Human Services, and Thomas Scully in his capacity as Administrator of the Centers for Medicare and Medicaid Services (formerly Administrator of the Health Care Financing Administration),

Appellants

SUR PETITION FOR REHEARING EN BANC

BEFORE: SCIRICA, SLOVITER, NYGAARD, ALITO, ROTH, MCKEE, RENDELL, BARRY, AMBRO, FUENTES, SMITH and CHERTOFF *Circuit Judges*

The petition for rehearing on behalf of Appellee in the above-entitled case, having been submitted to the judges who participated in the decision of this court and to all other

available circuit judges in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges in regular active service not having voted for rehearing by this court en banc, the petition for rehearing en banc is hereby **DENIED**.

IT IS SO ORDERED

By the Court,

/s/ Hon. Theodore A. McKee
Circuit Judge

DATED: December 16, 2003

APPENDIX D — STATUTES INVOLVED

42 U.S.C. § 405

§ 405. Evidence, procedure, and certification for payments

* * *

(g) Judicial review

Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia. As part of the Commissioner's answer the Commissioner of Social Security shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a

rehearing. The findings of the Commissioner of Social Security as to any fact, if supported by substantial evidence, shall be conclusive, and where a claim has been denied by the Commissioner of Social Security or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party to the hearing before the Commissioner of Social Security, because of failure of the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations. The court may, on motion of the Commissioner of Social Security made for good cause shown before the Commissioner files the Commissioner's answer, remand the case to the Commissioner of Social Security for further action by the Commissioner of Social Security, and it may at any time order additional evidence to be taken before the Commissioner of Social Security, but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Commissioner of Social Security shall, after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm the Commissioner's findings of fact or the Commissioner's decision, or both, and shall file with the court any such additional and modified findings of fact and decision, and a transcript of

the additional record and testimony upon which the Commissioner's action in modifying or affirming was based. Such additional or modified findings of fact and decision shall be reviewable only to the extent provided for review of the original findings of fact and decision. The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions. Any action instituted in accordance with this subsection shall survive notwithstanding any change in the person occupying the office of Commissioner of Social Security or any vacancy in such office.

(h) Finality of Commissioner's decision

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

* * * *

Appendix D

42 U.S.C. § 1395ii

§ 1395ii. Application of certain provisions of subchapter II

The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (*l*) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II of this chapter, except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

Appendix D

42 U.S.C. § 1395y

§ 1395y. Exclusions from coverage and medicare as secondary payer

* * *

(b) Medicare as secondary payer

* * *

(2) Medicare secondary payer

(A) In general

Payment under this subchapter may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that—

(i) payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under paragraph (1), or

(ii) payment has been made or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a State or under an automobile or liability

insurance policy or plan (including a self-insured plan) or under no fault insurance.

In this subsection, the term "primary plan" means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies. An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

(B) Repayment required

(i) Authority to make conditional payment

The Secretary may make payment under this subchapter with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be

expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.

(ii) Primary plans

A primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this subchapter with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means.

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If reimbursement is not made to the appropriate Trust Fund before the expiration of the 60-day period that begins on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received, the Secretary may charge interest (beginning with the date on which the notice or other information is received) on the amount of the reimbursement until reimbursement is made (at a rate determined by the Secretary in accordance with regulations of the Secretary of the Treasury applicable to charges for late payments).

(iii) Action by United States

In order to recover payment made under this subchapter for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion

thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity. The United States may not recover from a third-party administrator under this clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and is not employed by or under contract with the employer or group health plan at the time the action for recovery is initiated by the United States or for whom it provides administrative services due to the insolvency or bankruptcy of the employer or plan.

(iv) Subrogation rights

The United States shall be subrogated (to the extent of payment made under this subchapter for such an item or service) to any right under this subsection of an individual or any

other entity to payment with respect to such item or service under a primary plan.

(v) Waiver of rights

The Secretary may waive (in whole or in part) the provisions of this subparagraph in the case of an individual claim if the Secretary determines that the waiver is in the best interests of the program established under this subchapter.

(vi) Claims-filing period

Notwithstanding any other time limits that may exist for filing a claim under an employer group health plan, the United States may seek to recover conditional payments in accordance with this subparagraph where the request for payment is submitted to the entity required or responsible under this subsection to pay with respect to the item or service (or any portion thereof) under a primary plan within the 3-year period beginning on the date on which the item or service was furnished.

Appendix D

(C) Treatment of questionnaires

The Secretary may not fail to make payment under subparagraph (A) solely on the ground that an individual failed to complete a questionnaire concerning the existence of a primary plan.

* * * *

APPENDIX E — GOVERNMENT ADJUDICATION LETTER TO CLASS MEMBER FOR MSP CLAIMS DATED MAY 7, 2001

HCFA
Health Care Financing Administration

MEDICARE
Part A Intermediary
Phone (805) 367-1173

May 7, 2001

Re: HICN 336243721a
Date of Injury: 5/26/1993

Medicare has determined that you are required to reimburse the Medicare program **$11,833.44** for amounts it paid for items or services relating to your orthopedic bone screw settlement with AcroMed Corporation. Federal law requires Medicare beneficiaries who obtain a liability recovery to repay the United States the amount the Medicare program paid for conditions related to that recovery. This responsibility to reimburse Medicare arises upon payment of the funds by a third party regardless of whether liability or causation is established at trial or otherwise. (For Medicare's right to recover, see 42 U.S.C. § 1395y(b)(2) and 42 C.F.R Part 411 beginning at § 411.20.)

The Department of Justice's efforts to negotiate a global settlement of Medicare's claims with the Plaintiffs Legal Committee were brought to a halt when the AcroMed Settlement Class representative brought suit against the Medicare program. Consequently, we are now sending

individual demands for repayment to Medicare benefciaries involved in the settlement. We are sending a copy of this letter to the Plaintiffs Legal Committee. If you have retained a separate personal attorney, please provide us with your attorney's name and address immediately so that we may send your attorney a copy of this letter. Please use the enclosed form and envelope to provide this information to us.

A list of the payments the Medicare program made to you or on your behalf is enclosed. The Medicare program paid **$33,737.95** for items and services related to your orthopedic bone screw settlement. We have reduced this amount to **$11,833.44** in accordance with the regulatory formula found at 42 C.F.R. § 411.37. This includes a reduction to reflect the costs you incurred to procure the settlement. We based our calculation on the following information:

Gross Settlement Amount: **$16,792.38** Fees You Paid to the Plaintiffs Legal Committee: **$2,015.08** Costs You Paid to the Plaintiffs Legal Committee: **$839.62** Fees You Paid to your Personal Attorney: **$1,679.24** Costs You Paid to your Personal Attorney: **$425.00** Date of First Implantation of an AcroMed Spinal Fixation Device: **5/26/1993**

You must notify us immediately if any of the above information is incorrect because the amount you owe Medicare may change.

The amount you owe Medicare may also change if the Medicare program must litigate to collect the amount it is owed. In that case, Medicare's claim for repayment is subject to the regulation found at 42 C.F.R. § 411.37(e), which

authorizes Medicare to recover an amount equal to either the total amount of the Medicare conditional payments made on your behalf or the total amount of your settlement minus the total amount of attorneys' fees and costs you paid, whichever is less.

This demand relates only to your proceeds from your orthopedic bone screw settlement with AcroMed Corporation. If, in the future, you receive additional funds from this settlement, or any other settlement, judgment, or award, you must notify the Medicare program. The Medicare program will then determine whether you must repay any additional funds.

You must pay this amount **($11,833.44)** within sixty (60) days of the date of this letter (by **July 9, 2001).** Please send a check or money order in the amount of **$11,833.44** made payable to Medicare to the address shown at the end of this letter.

If you do not pay this amount by **July 9, 2001,** you will be required to pay interest from the date of this letter. Interest will be calculated at the rate of **13.75%** per annum in accordance with 42 C.F.R 411.24(m). Interest will continue to accrue until the debt is paid, whether or not a waiver of recovery request or appeal is pending.

If you do not pay this amount, the Medicare program may recover the amount from any Social Security or Railroad Retirement benefits to which you might otherwise be entitled, or the money may be recouped from payments Medicare would otherwise pay you. Also, please be aware that Medicare

must refer delinquent debts to the Department of the Treasury for offset against Federal payments that may be due or for other appropriate collection actions.

If you are unable to pay this amount in one payment, you may ask us to consider whether to allow you to pay in regular installments. (Any installment payments are applied to accrued interest first and then to the remaining principal.)

You have the right to request that the Medicare program waive its recovery in whole or in part. The Medicare program may waive its recovery if **both** of the following conditions are met:

1. This overpayment (for purposes of requesting waiver of recovery, the amount you owe is considered an overpayment), was not your fault, because the information you gave us with your claims for Medicare benefits was correct and complete as far as you knew, and, when the Medicare payment was made, you thought that it was the right payment,

   AND

2. Paying back this money would cause financial hardship OR would be unfair for some other reason.

If you believe that **BOTH** of the conditions above apply in your case, you should make a written request for waiver of recovery of the overpayment within thirty (30) days of the date of this letter, giving a brief statement of your reasons. Your request should be sent to United Government Services

at the address shown at the end of this letter. You will be sent a form asking for information about your income, assets, and expenses, and requesting that you explain why you believe you are entitled to waiver of recovery. We will notify you if recovery of some or all of the amount you owe can be waived. If Medicare is unable to grant your waiver of recovery request, you will be afforded appeal rights on the waiver determination.

You may appeal our determination that you owe **$11,833.44** related to your orthopedic bone screw settlement, judgment, or award. For Part A services, you must appeal within sixty (60) days from the date of your receipt of this determination. For Part B services, you must file an appeal within six (6) months of the date of this determination. However, we recommend that you file appeals of Part A and Part B claims within sixty (60) days of receiving this notice so that both appeals may be resolved efficiently. To appeal, you should send your request in writing to United Government Services at the address shown at the end of this letter. (Appeals may be filed with the Health Care Financing Administration, including Medicare contractors, or the Social Security Administration. However, as your request will be forwarded to our office regardless of where it is filed, mailing it to us directly is faster and more efficient.)

If you decide to appeal this determination further, and if you want help with your appeal, you can have a friend, lawyer, or someone else help you. Some lawyers do not charge unless you win your appeal. There are groups, such as lawyer referral services, that can help you find a lawyer. There are also groups, such as legal aid services, who will provide free legal services if you qualify.

Appendix E

If you have any questions about this letter, you may call either of the following dedicated BoneScrew phone lines and your call will be returned within two business days: (805) 367-1173 or (805) 367-0668.

Sincerely,

The Medicare Secondary Payer Unit
United Government Services, LLC
P. O. Box 9140
Oxnard, CA 93031-9140

Attachment: List of items and services included in Medicare's recovery claim Form for use in providing personal attorney information

Appendix E

PLEASE USE THIS FORM TO PROVIDE US WITH THE NAME AND ADDRESS OF YOUR PERSONAL ATTORNEY.

Please provide the name, address, and phone number of your personal attorney below. We will use this information to send your attorney a copy of the enclosed letter. When you have completed this form, please mail it to us in the enclosed envelope. (Send this page only, and keep the letter for your records.)

LORETTA J GOYKE
1103 6TH ST
PAWNEE IL
62558

HICN 336243721A

Attorney's Name _____

Attorney's Address: _____

_____

Attorney's Phone Number: _____

APPENDIX F — AFFIDAVIT DATED JUNE 4, 2001

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Civil Action
No.: 01-CV-1029

Daniel C. Fanning

v.

The United States Of America, *et al.*

AFFIDAVIT

STATE OF MICHIGAN)
) ss.
COUNTY OF MONTMORENCI)

Michael Bohuni cki being duly sworn according to law deposes and says:

1. I am a member of the class of individuals that entered into a class action Settlement Agreement with AcroMed Corporation on January 8, 1997. *See In Re*: *Orthopedic Bone Screw Product Liability Litigation*, 176 F.R.D. 158 (E.D.Pa. 1997).

2. I am a member of the AcroMed Settlement class by virtue of the fact that I was implanted with an AcroMed pedicle screw fixation device on or before December 31, 1996.

3. I am unable to be present at this Court's hearing scheduled for June 6, 2001 to testify in support of Plaintiffs' Motion for because I do not reside in Pennsylvania and traveling to Philadelphia, PA, would present a great hardship due to my physical condition.

4. Thus, I am submitting this affidavit in lieu of testifying before the court.

5. On or about May 7, 2001, I received an Adjudication letter from Health Care Financing Administration (HCFA) that demanded reimbursement to the Medicare program in the sum of $2,102.91, for amounts the government represented that it paid for items or services related to my orthopedic bone screw settlement with AcroMed corporation.

6. The Adjudication enclosed a purported list of payments that the Medicare program allegedly made for my benefit.

7. Prior to the transmission of the Adjudication letter, HCFA did not provide me with notice of the potential adjudication of reimbursement claims or an opportunity to demonstrate that I had no reimbursement liability.

8. It is my contention that I am not responsible to reimburse Medicare in the amounts demanded in the Adjudication letter because:

_____ I never received the services for which Medicare is seeking reimbursement; and/or

Appendix F

_____ Medicare did not pay for the items or services for which reimbursement is sought; and/or

_____ Medicare was already reimbursed for some or all of the items or services for which reimbursement is sought; and/or

__X__ The items or services for which Medicare is seeking reimbursement are unrelated to any injury allegedly caused to me by the AcroMed Spinal Fixation Device; and/or

_____ I have no reimbursement liability because:

s/ Michael Bohunicki
Michael Bohunicki

APPENDIX G — AFFIDAVIT DATED JUNE 2, 2001

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Civil Action
No.: 01-CV-1029

Daniel C. Fanning

v.

The United States Of America, *et al.*

AFFIDAVIT

STATE OF FLORIDA)
) ss.
COUNTY OF CITRUS)

KENNETH DALBOW being duly sworn according to law deposes and says:

1. I am a member of the class of individuals that entered into a class action Settlement Agreement with AcroMed Corporation on January 8, 1997. *See In Re: Orthopedic Bone Screw Product Liability Litigation*, 176 F.R.D. 158 (E.D.Pa. 1997).

2. I am a member of the AcroMed Settlement class by virtue of the fact that I was implanted with an AcroMed pedicle screw fixation device on or before December 31, 1996.

3. I am unable to be present at this Court's hearing scheduled for June 6, 2001 to testify in support of Plaintiffs' Motion for because I do not reside in Pennsylvania and traveling to Philadelphia, PA, would present a great hardship due to my physical condition.

4. Thus, I am submitting this affidavit in lieu of testifying before the court.

5. On or about May 7, 2001, I received an Adjudication letter from Health Care Financing Administration (HCFA) that demanded reimbursement to the Medicare program in the sum of $20,821.72, for amounts the government represented that it paid for items or services related to my orthopedic bone screw settlement with AcroMed corporation.

6. The Adjudication enclosed a purported list of payments that the Medicare program allegedly made for my benefit.

7. Prior to the transmission of the Adjudication letter, HCFA did not provide me with notice of the potential adjudication of reimbursement claims or an opportunity to demonstrate that I had no reimbursement liability,

8. It is my contention that I am not responsible to reimburse Medicare in the amounts demanded in the Adjudication letter because:

_____ I never received the services for which Medicare is seeking reimbursement; and/or

Appendix G

_____ Medicare did not pay for the items or services for which reimbursement is sought; and/or

_____ Medicare was already reimbursed for some or all of the items or services for which reimbursement is sought; and/or

__XX__ The items or services for which Medicare is seeking reimbursement are unrelated to any injury allegedly caused to me by the AcroMed Spinal Fixation Device; and/or

_____ I have no reimbursement liability because:

_____ I have only received $10,410.86 in this settlement todate.

s/ Kenneth S. Dalborn

APPENDIX H — AFFIDAVIT DATED JUNE 1, 2001

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Civil Action
No.: 01-CV-1029

Daniel C. Fanning

v.

The United States Of America, *et al.*

AFFIDAVIT

STATE OF Ohio)
) **ss.**
COUNTY OF Lorain)

Ignacio Chavez being duly sworn according to law deposes and says:

1. I am a member of the class of individuals that entered into a class action Settlement Agreement with AcroMed Corporation on January 8, 1997. *See In Re*: *Orthopedic Bone Screw Product Liability Litigation*, 176 F.R.D. 158 (E.D.Pa. 1997).

2. I am a member of the AcroMed Settlement class by virtue of the fact that I was implanted with an AcroMed pedicle screw fixation device on or before December 31, 1996.

3. I am unable to be present at this Court's hearing scheduled for June 6, 2001 to testify in support of Plaintiffs' Motion for because I do not reside in Pennsylvania and traveling to Philadelphia, PA, would present a great hardship due to my physical condition.

4. Thus, I am submitting this affidavit in lieu of testifying before the court.

5. On or about May 7, 2001, I received an Adjudication letter from Health Care Financing Administration (HCFA) that demanded reimbursement to the Medicare program in the sum of $3,486.62, for amounts the government represented that it paid for items or services related to my orthopedic bone screw settlement with AcroMed corporation.

6. The Adjudication enclosed a purported list of payments that the Medicare program allegedly made for my benefit.

7. Prior to the transmission of the Adjudication letter, HCFA did not provide me with notice of the potential adjudication of reimbursement claims or an opportunity to demonstrate that I had no reimbursement liability.

8. It is my contention that I am not responsible to reimburse Medicare in the amounts demanded in the Adjudication letter because:

_____ I never received the services for which Medicare is seeking reimbursement; and/or

Appendix H

__X__ Medicare did not pay for the items or services for which reimbursement is sought; and/or

_____ Medicare was already reimbursed for some or all of the items or services for which reimbursement is sought; and/or

_____ The items or services for which Medicare is seeking reimbursement are unrelated to any injury allegedly caused to me by the AcroMed Spinal Fixation Device; and/or

__X__ I have no reimbursement liability because: this was a Workers' Compensation matter only.

s/ Ignacio J. Chavez

APPENDIX I — EXCERPTS OF TESTIMONY IN PRELIMINARY INJUNCTION HEARING IN IN RE ORTHOPEDIC BONE SCREW PRODUCTS LIABILITY LITIGATION, MDL NO. 1014 DATED JUNE 6, 2001

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW LITIGATION

MDL DOCKET NO. 10145CREW PRODUCTS LIABILITY
ALL CASES

PHILADELPHIA, PA.

JUNE 6, 2001

BEFORE HON. LOUIS C. BECHTLE, CH. J. EMERITUS

(Commencing at page 79 . . .)

* * *

MR. FISHBEIN: At this time, we would like to call Charlene DeLorenzo. She is in a wheelchair. It may take a bit of time.

THE COURT: What we can do is come forward to the well of the Court here, and testify right there in front of counsel table. That would be good. Thank you. If you want it, move to this table. It would be more convenient. Feel free to move.

Appendix I

Can you please tell us your full name, please?

THE WITNESS: Charlene DeLorenzo.

THE COURT: Please spell your last name.

THE WITNESS: D-E-L-O-R-E-N-Z-O.

CHARLENE DeLORENZO, SWORN.

[80] THE COURT: You may proceed.

MR. FISHBEIN: Thank you, your Honor.

DIRECT EXAMINATION

BY MR. FISHBEIN:

* * *

[81] Q. Have you been determined to be disabled?

A. Yes, I have.

Q. Who made that determination?

A. Social Security Administration and also my auto insurance carrier.

Q. Did your back problems start with an automobile accident?

A. Yes, it did.

Q. Are you in any way dependent upon Social Security or Medicare for your support or payment of your medical bills?

A. Yes, I am. I receive SSD wages or — in that form. I'm sorry. The pain is getting to me. Maybe I didn't quite understand your question. I got distracted there.

Q. No, you didn't. You are receiving Social Security disability payments?

[82] A. Yes.

Q. Did you apply to receive payment from the AcroMed Settlement Fund?

A. Yes, I did.

Q. Was your application processed?

A. Yes, it was.

Q. Have you received a payment from the AcroMed Settlement Fund?

A. A partial.

Q. When was that?

A. I don't remember the exact date. I know recently somewhere around $9,000.

Q. You netted $9,000?

A. Yes. It was partial, so somewhere around 9.

Q. Do you expect to receive further payments in the future from the fund?

A. Yes, I do.

Q. Now, you have been sitting patiently throughout the proceedings. I can tell it is taking a toll on you. But did you receive one of these letters on May 7th of 2001?

A. Yes.

* * *

[83] Q. Were you able to examine and understand the list of Medicare payments which is attached to the letter?

A. The list stated by Mr. Welsh is the only thing you can go by, the date of service and the amount, in order to find out who the doctor or the provider was. It took a lot of time to figure this out.

Q. Did you keep your medical bills going back to the period of time covered by this which is —

A. Very fortunately.

Q. As a result of your review, including your review of the medical records, were you able to determine whether or not the government statement that these charges were paid by the Medicare program for items and services related to your orthopedic bone screw settlement was a correct statement or not?

[84] A. If most of it was incorrect. Most of them were not related. We had things like internal medicine doctors, one ER visit for bladder infection on here, lab work, nothing to do — blood work, nothing to do with my back. You know, that was mainly what I saw was in error, along with the amounts given compared to what I had of record.

Q. So they were basically saying that amounts paid for treating the bladder infection, things of that nature, were Medicare treatments related to your orthopedic bone screw related problems?

A. Yes. Internal medicine doctors, a lot of times it was for a cold, general health interests. How they could even put those items down?

Q. Were you able to determine whether, in fact, the Medicare program actually paid for any of the items that were on this list?

A. They showed their payments here. Some of them are correct, some are not. According to my records, my auto carrier paid for the part of anything that had to do with my lumbar spine or with my neck. These items here, I just don't — anything here, nothing of which would go back to Medicare. Everything has been paid.

Q. By your auto carrier?

[85] A. By my auto carrier, as far as my back is concerned, yes.

Q. Can you describe for the Court what impact the receipt of this letter had on you when you received it?

A. I was distressed for the simple reason the format here, they didn't list the doctors. I had to search high and low to figure out what this even pertained to. The numbers were off. You know, it was just really painstaking for me in my condition to have to go through the archives of my medical records to try to match this all up, to try to figure out what they did as far as discovery, it was really a difficult task for me.

Q. Can you afford to plunk down $750 to the government at this point in time?

A. No, I don't see where I owe it, nor can I. I'm unable to work, dependent on Social Security checks on a monthly basis. I really hated to be threatened to have a levy or have my benefits taken away to pay for this. I had no idea that Social Security had a problem of any sort. If they would have contacted me on these items, I could have looked it up and told them, but no one contacted me outside of this threat letter and this list. It was very difficult.

* * * *

(3)

Supreme Court, U.S.
FILED
MAY 19 2004
OFFICE OF THE CLERK

No. 03-1327

In the Supreme Court of the United States

DANIEL C. FANNING, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

THEODORE B. OLSON
Solicitor General
Counsel of Record
PETER D. KEISLER
Assistant Attorney General
MARK B. STERN
ALISA B. KLEIN
Attorneys
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

BEST AVAILABLE COPY

QUESTION PRESENTED

Petitioner brought this class action to enjoin the federal government from seeking reimbursement pursuant to the Medicare Secondary Payer statute, 42 U.S.C. 1395y(b)(2), for Medicare payments made on behalf of Medicare beneficiaries who were members of class who participated in a class-action settlement. The question presented is whether the court of appeals correctly held that the district court lacked jurisdiction over their claims under 42 U.S.C. 405(h) because petitioner had not channeled their claims through the agency's administrative adjudication procedure.

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In the Supreme Court of the United States

No. 03-1327

DANIEL C. FANNING, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-35a) is reported at 346 F.3d 386. The opinion of the district court (Pet. App. 36a-79a) is reported at 202 F.R.D. 154.

JURISDICTION

The judgment of the court of appeals was entered on October 10, 2003. A petition for rehearing was denied on December 16, 2003 (Pet. App. 80a-82a). The petition for a writ of certiorari was filed on March 15, 2004. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Petitioner brought this class action to enjoin the federal government from seeking reimbursement pursuant to the Medicare Secondary Payer (MSP) statute, 42 U.S.C. 1395y(b)(2), for the Medicare payments the government had made on behalf of Medicare beneficiaries who were members of a class in a class-action suit that was settled.

The MSP statute was amended in 1980 (Pub. L. No, 96-499, § 308(a), 94 Stat. 531) to curb rising Medicare costs. H.R. Rep. No. 1167, 96th Cong., 2d Sess. 352 (1980); *Zinman* v. *Shalala*, 67 F.3d 841, 843, 845 (9th Cir. 1995). The statute was designed to lower overall federal Medicare disbursements by requiring Medicare beneficiaries to exhaust all available insurance coverage before resorting to their Medicare coverage. *United States* v. *Rhode Island Insurers' Insolvency Fund*, 80 F.3d 616, 618 (1st Cir. 1996).

When an insurer under a primary plan makes a payment to a Medicare beneficiary with respect to medical care for which the Medicare program has already paid, a duplicate payment results. Absent reimbursement to Medicare, that duplicate payment results in a Medicare overpayment by operation of the MSP statute. 42 C.F.R. 405.704(b)(13); *Buckner* v. *Heckler*, 804 F.2d 258, 259 (4th Cir. 1986); H.R. Rep. No. 432, 98th Cong., 2d Sess. 1803 (1984).

A beneficiary who disagrees with the Secretary's determination that he or she received an overpayment is entitled to a hearing before the Secretary as provided in 42 U.S.C. 405(b). 42 U.S.C. 1395ff(b)(1). A beneficiary who is dissatisfied with a final decision of the Secretary after such a hearing is entitled to judicial

review of that decision, as provided in 42 U.S.C. 405(g). 42 U.S.C. 1395ff(b)(1).

The beneficiary also may ask the Secretary to waive recovery in full or in part. The Secretary may waive recovery when the beneficiary was not at fault and recovery would defeat the purposes of the Medicare Act or be against equity or good conscience. 42 U.S.C. 1395gg(c). The regulations provide that the purposes of the Medicare Act would be defeated if the Secretary's recovery would deprive a person of income required for ordinary and necessary living expenses, including medical expenses. 42 C.F.R. 405.358, 405.508(a). The Secretary's waiver determination is subject to administrative and judicial review. 42 U.S.C. 1395ff(b)(1); 42 C.F.R. 405.704(b)(14), 405.720-405.730.

The second and third sentences of Section 205(h) of Title II of the Social Security Act, 42 U.S.C. 405(h), made applicable to the Medicare Act by 42 U.S.C. 1395ii, provide:

> No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

2. This case arises out of the 1997 settlement of mass tort litigation against AcroMed Corporation, a manufacturer of orthopedic bone screws used in spinal fusion surgery. Pet. App. 6a-7a; see *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001) (describing proceedings). When the United States learned of the proposed settlement, it informed the settling parties that, to the extent the government had made Medicare

payments for the class members' bone screw settlement-related medical care, the Medicare Secondary Payer statute required that Medicare be reimbursed. Pet. App. 7a. The final settlement agreement required AcroMed to pay $100 million into a settlement fund for distribution to class members who qualified for payment in accordance with a procedure to be established by the court. *Ibid.* The settlement agreement did not provide for reimbursement of the government's Medicare payments.

Efforts to settle the government's claims failed when petitioner filed this class action lawsuit, seeking to enjoin the federal government from taking any action to recover Medicare payments from members of the class. The government ultimately sent letters to approximately 1800 Medicare beneficiaries in the AcroMed settlement class that notified each of the beneficiaries of Medicare's claim and that indicated the particular amount of reimbursement that was required.* The letters noted that interest would accrue if payment was not made in a timely fashion, and that the Medicare program has the right to recover unpaid amounts through offsets against other federal benefits. Pet. App. 96a.

The letters further explained that beneficiaries have the right to file an administrative appeal of the agency's determination that they are required to reimburse the Medicare program, and the letters set out the process for doing so. Pet. App. 98a. The letters also explained

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* The amount of reimbursement sought varied widely. For example, while the letter that petitioner has included in the petition appendix sought nearly $12,000, Pet. App. 94a, the government sought only $8.71 in reimbursement from Fanning himself. *Id.* at 45a.

that beneficiaries have the right to request that the Medicare program waive its recovery in whole or in part, and explained that the program may do so if the overpayment was not the beneficiary's fault and repayment would cause financial hardship or be unfair for some other reason. *Id.* at 97a.

The amended complaint (filed after the Secretary's letters were sent) alleged that, as a statutory matter, the payments made pursuant to the AcroMed settlement did not give the federal government a right to reimbursement under the MSP provisions. Pet. App. 8a. The complaint also alleged that the government's efforts to obtain reimbursement violated the class members' due process rights. *Id.* at 40a.

The government moved to dismiss the complaint for lack of subject matter jurisdiction because the class members had not presented their claims to the agency as required by 42 U.S.C. 405(g) and (h). The district court denied the motion. Pet. App. 36a-79a. The court reasoned that those provisions did not apply to petitioner's claims because the class members were not seeking to recover Medicare benefits but were instead seeking to enjoin the government from collecting funds it had already paid. *Id.* at 69a.

In the same ruling, the district court entered a preliminary injunction barring the government from taking any steps to obtain reimbursement for its Medicare payments from the class members. The court offered two statutory reasons for its conclusion that the payments from the AcroMed settlement did not trigger the federal government's right to reimbursement for its Medicare payments. Pet. App. 49a-66a. First, the court ruled that AcroMed could not be regarded as having a "self-insured plan" that was primary to Medicare under 42 U.S.C. 1395y(b)(2). Pet. App. 54a-60a. Second, the

court ruled that the government has no right to reimbursement because AcroMed could not reasonably have been expected to make "prompt" payment at the time Medicare paid for a class member's medical care under 42 U.S.C. 1395y(b)(2). Pet. App. 60a-66a. The court did not rely upon petitioner's due process claims as a separate basis for the injunction or otherwise address those claims.

3. A unanimous panel of the Third Circuit reversed, holding that the district court lacked subject matter jurisdiction over the lawsuit. Pet. App. 1a-35a. The court concluded that, under 42 U.S.C. 405(h), challenges to the Secretary's overpayment determinations must be presented administratively before they may be heard in court. Pet. App. 11a-12a.

The court observed that this Court had already rejected the distinction, drawn by the district court, between actions to recover benefits and actions to preclude the government from collecting reimbursement for benefits already paid. Pet. App. 25a-28a (describing *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000)). The court likewise explained that, under this Court's precedents, a due process claim that is intertwined with a statutory claim to benefits must be presented to the agency, regardless of whether the agency would have discretion to consider the constitutional challenge. *Id.* at 13a-21a (describing *Weinberger* v. *Salfi*, 422 U.S. 749 (1975), and *Heckler* v. *Ringer*, 466 U.S. 602 (1984)).

Finally, the court of appeals explained that this case is unlike *Bowen* v. *Michigan Academy Family Physicians*, 476 U.S. 667 (1986), where the plaintiff had no avenue of administrative review. The court stressed that petitioner was "plainly wrong" in contending that class members had no right to administrative review of

the agency's demand for MSP reimbursement. Pet. App. 30a, 31a. The court observed that the letters sent to class members "clearly advised them of the administrative process by which they could appeal the agency's determination or, in the alternative, seek a waiver of Medicare's claim for reimbursement," a process that was likewise set out in the Medicare Intermediary Manual. *Id.* at 31a.

ARGUMENT

The court of appeals correctly held that the district court lacked subject matter jurisdiction over this lawsuit because the class members have not presented their claims to the agency. Petitioner does not allege a conflict with the decision of another court of appeals. The petition should thus be denied.

1. As this Court has explained, related provisions of the Medicare and Social Security Acts "channel[] most, if not all, Medicare claims through [a] special review system" that requires that claims be presented administratively before judicial review may be sought. *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 8 (2000). Under 42 U.S.C. 405(g), only final decisions of the Secretary are subject to judicial review in federal district court. Section 405(h) makes that avenue of judicial review exclusive, by providing that "[n]o action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter." 42 U.S.C. 405(h). Pursuant to 42 U.S.C. 1395ii, Section 405(h) applies to the Medicare Act to the same extent that it applies to the Social Security Act. *Illinois Council*, 529 U.S. at 8-9.

As the court of appeals observed, this Court has repeatedly rejected efforts to read Section 405(h) narrowly. Thus, in *Weinberger* v. *Salfi*, 422 U.S. 749, 760-761 (1975), the Court held that due process and equal protection challenges to a statutory condition on receipt of survivor's benefits must be channeled through the agency because the Social Security Act provided both the standing and the substantive basis for the claim to benefits. Likewise, in *Heckler* v. *Ringer*, 466 U.S. 602, 614-615 (1984), the Court held that an effort to enjoin a Medicare policy on due process grounds must be channeled through the agency. In *Illinois Council*, the Court confirmed that it would not "accept a distinction that limits the scope of [Section] 405(h) to claims for monetary benefits." 529 U.S. at 14.

Under those decisions, the class members were required to channel their challenges to the agency's overpayment determinations through the agency. The Medicare Act provides both the standing and substantive basis for the claims, which in "essence" allege that the Medicare payments made on behalf of class members should be treated as primary, rather than secondary, to the payments made under the AcroMed settlement. As the court appeals correctly explained:

> [T]he claim asserted in the amended class action complaint is wholly dependent upon determining whether or not AcroMed is a "self-insured plan" and, therefore, a "primary plan" under the MSP. It is thus apparent that both the standing and the substantive basis for the claim asserted in the amended class action complaint are rooted in, and derived from, the Medicare Act.

Pet. App. 29a-30a (footnote omitted).

2. The petition does not discuss the statutory claims that provided the basis for the district court's injunction, but focuses exclusively on the due process claims that the district court did not address. The petition urges that, to the extent the class has presented procedural due process challenges to the letters sent to class members, the class could not have obtained adequate relief from the agency, and that therefore class members should have been entitled to bring their constitutional challenges in a suit based on 28 U.S.C. 1331, outside the exclusive review provisions of 42 U.S.C. 405. Pet. 12. That contention, however, is foreclosed by this Court's decision in *Weinberger* v. *Salfi*, 422 U.S. at 764, which held that determinations by the Secretary which are allegedly unconstitutional and "which are beyond the power of the Secretary to affect" are nonetheless decisions that must be channeled through the agency under Section 405(h). And in *Mathews* v. *Eldridge*, 424 U.S. 319, 326-332 (1976), the Court made clear that 42 U.S.C. 405(g) provides the only avenue for judicial review even where, as here, the claimant raises a procedural due process challenge to the administrative procedures used by the agency in denying benefits. See also *Califano* v. *Yamasaki*, 442 U.S. 682 (1979) (suit properly brought under 42 U.S.C. 405(g) to challenge procedures for determining whether an overpayment of Social Security benefits had occurred and whether a waiver of recoupment should be granted.)

Moreover, this Court should not consider petitioner's contention because it was not passed upon below. Before the court of appeals, petitioner below did not distinguish between the statutory and constitutional claims. Instead, petitioner urged that the class members had no administrative appeal rights for *any* of

their claims because the government's administrative determinations were themselves not authorized by the MSP statute. See, *e.g.*, C.A. Br. 37 ("Congress only authorized the Government to recover payments it made as an alleged statutory secondary payer by bringing a civil action in court and not through administrative adjudication."). The court of appeals properly rejected that contention in light of the established administrative procedures used in processing appeals of MSP overpayment and waiver determinations. Pet. App. 31a. That ruling also is consistent with the decisions of the other courts of appeals addressing the issue. *Cochran* v. *Health Care Fin. Admin.*, 291 F.3d 775 (11th Cir. 2002) (dismissing suit challenging MSP liability because beneficiary had failed to exhaust her administrative remedies); *Buckner* v. *Heckler*, 804 F.2d 258 (4th Cir. 1986) (same).

In any event, petitioner's due process claims rest on a faulty premise. The petition purports to argue that the government has deprived class members of property without providing a pre-deprivation opportunity to challenge the agency's overpayment determinations. Pet. 9-13. The Secretary's letters sent out to the class, however, clearly explained that a beneficiary may challenge the agency's determination administratively and/or seek a waiver. There also is no evidence in the record suggesting that the government has attempted or would attempt to recover reimbursement (through offset or otherwise) while a class member's administrative appeal or waiver request is pending. Moreover, the Secretary's administrative procedures would provide petitioner and those class members similarly situated with precisely the type of avenue petitioner says is necessary to determine whether class members received an overpayment under Medicare, for which the

beneficiary is liable to the Secretary under the MSP. See, *e.g.*, Pet. 10-11. The petition thus presents no issue warranting this Court's review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

THEODORE B. OLSON
Solicitor General
PETER D. KEISLER
Assistant Attorney General
MARK B. STERN
ALISA B. KLEIN
Attorneys

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IN THE

Supreme Court of the United States

MERCK KGAA,

Petitioner,

v.

INTEGRA LIFESCIENCES I, LTD. and THE BURNHAM INSTITUTE, and TELIOS PHARMACEUTICALS, INC.,

Respondents.

On Petition for Writ of Certiorari To the United States Court of Appeals For the Federal Circuit

MOTION FOR LEAVE TO FILE AND BRIEF FOR *AMICUS CURIAE* ELI LILLY AND COMPANY IN SUPPORT OF PETITIONER

William R. Boudreaux
Counsel of Record
James J. Kelley
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
(317) 276-0755

April 1, 2004

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MOTION OF ELI LILLY AND COMPANY FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER MERCK KGAA

Pursuant to Sup. Ct. Rule 37.2(b), *amicus* - Eli Lilly and Company – moves for leave to file the attached brief *Amicus Curiae* in support of Petitioners seeking review of *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003).

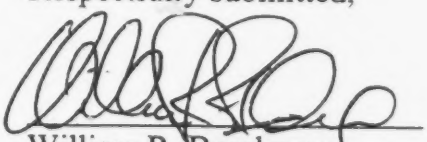
In the decision below, a divided panel of the Federal Circuit ruled that certain pre-clinical development activities that were not "reasonably related to clinical tests for the FDA" were not entitled to the safe harbor exemption to patent infringement provided by 35 U.S.C. §271(e)(1). The extent of the Federal Circuit's holding is unclear, as is what sort of drug development activity is exempt from infringement and what is not. The majority panel's original decision appeared to state that no activity relating to innovative or pioneering drugs would be entitled to the safe

harbor exemption. However, since such a holding would be contrary to established Supreme Court precedent, the majority panel subsequently published an errata sheet to attempt to clarify its holding. Even after the publication of the errata sheet, innovator *and* generic drug companies are left to guess what studies they conduct or data they generate would expose them to claims for patent infringement. Such uncertainty will quell drug development and provide a *de facto* extension of term for certain classes of patents – a result that was considered by this Court to be a "distortion" of the statute and of Congress' intent.

Amicus is a research-based pharmaceutical company that discovers and develops innovative therapeutic and biopharmaceutical products and has recognized expertise in the drug development process. This brief is offered to provide an analysis of the legal error committed by the majority panel, a basic description of the drug development process, and an explanation of the risks that this decision poses to stifling new drug development.

While Respondents did provide verbal consent for *amicus* to file this brief in support of Petitioners, this motion is deemed to be necessary since the deadline for filing is imminent and *amicus* has not yet received written consent as required by the rules.

Respectfully submitted,



William R. Boudreaux
Counsel of Record
ELI LILLY AND COMPANY
Lilly Corporate Center
Indianapolis, Indiana 46285
(317) 276-0755

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I. INTEREST OF AMICUS CURIAE*

Eli Lilly and Company ("Lilly") is a research-based pharmaceutical company that discovers and develops innovative products and services enabling people to live longer, healthier, and more active lives. If non-clinical development activities associated with the development of new drugs do not fall within the 271(e)(1) exemption, then development of some drugs will be substantially delayed and in some cases may not even occur. A patent covering enabling technology used in the development of a new chemical entity can potentially block drug development, and the patent holder may be unable or unwilling to license the patent or develop a drug on its own. Without sufficient freedom to conduct non-clinical research, development and approval of many new drugs will not occur. Without new drugs, there can be no generic equivalents.

Lilly has no stake in the parties in this litigation or in the result in the case, other than the fundamental interest in the case set out above. The parties to the case have not contributed in any way to the preparation of this *amicus* brief.

Mr. Robert A. Armitage was an expert for Petitioner Merck KgaA, and he is now General Counsel of *Amicus Curiae* Eli Lilly and Company. Mr. Armitage did not contribute to drafting or reviewing this brief.

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* The parties verbally consented to the filing of this brief; but written consent of Respondent was not received in time. Therefore a Motion for Leave to File accompanies this brief. This brief was not authored in whole or in part by counsel for a party, and no person or entity, other than the *amicus curiae* made a monetary contribution to the preparation and submission of this brief.

II. INTRODUCTION

Under the Federal Circuit's holding in this case, non-clinical activity may not be entitled to the Hatch-Waxman safe harbor exemption to patent infringement. This holding is contrary to established Supreme Court and Federal Circuit precedent, and also to the wording and purpose of the statute, which provides that "it shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention...solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. §271(e)(1).

If the Federal Circuit holding can be construed to exclude non-clinical activity from the ambit of the statute and that a patent can be used to exclude *in vivo* drug testing, the majority has created a conflict with Supreme Court precedent. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 666 (1990) ("[T]he safe harbor provision covers the "entire statutory scheme of regulation") and its own precedent. *See also AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997) ("The statute, therefore, does not look to the underlying purposes or attendant consequences of the activity . . . as long as the use is reasonably related to FDA approval"). It would also be contrary to lower court holdings demonstrating an established standard of practice, including one case affirmed by the Federal Circuit. *See, e.g., Intermedics v. Ventritex Co.*, 775 F. Supp. 1269 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104 (D. Mass. 1998). If antecedent activities that are necessary, though perhaps not usually reportable or reported, are not entitled to the

safe harbor exemption, then drug developers would be prevented from ever getting to protected activities. The Federal Circuit has, in one interpretation of the ruling, gutted the exemption for new drugs. This will have a devastating effect on advances in human medicine and, ironically, the cost of generic drugs, because generic drugs can only exist after a new drug has been created and marketed for a period of time.

The Supreme Court has stated that the privileges bestowed by patents are not unlimited and that the owner's pecuniary interest is weighed in light of public policy. *See Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 429 (1984) ("The monopoly privileges that Congress may authorize are neither unlimited nor primarily designed to provide a special private benefit . . . [and] . . . makes reward to the owner a secondary consideration"). The Federal Circuit's holding has provided a *de facto* extension of Integra's compound and tool patents and delays new drug development and new cures for patients. The Federal Circuit did not consider this resulting harm to patients when it excluded a significant portion of new drug discovery and development activities from the 271(e)(1) safe harbor. These harms are significant and clearly outweigh the interest in a patent right or any pecuniary benefits gained by patentees who have secured a *de facto* extension of their patent terms by enjoining non-clinical development necessary for FDA approval.

III. REASONS FOR GRANTING THE WRIT

A. The Lower Court's Holding Conflicts with Supreme Court Precedent, and with the Plain Meaning of and Purpose for 35 U.S.C. §271(e)(1).

The majority's opinion, despite the errata that attempts to remedy the clear errors in the original opinion, may restrict the protection of 271(e)(1) to generic drug companies, contrary to the Court's precedent and the plain meaning of 35 U.S.C. §271(e)(1). For example, the court states that one of two "reasons" for the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("the 1984 Act") was "to ensure that a patentee's rights did not *de facto* extend past the expiration of the patent term because a generic competitor also could not enter the market without regulatory approval." *Integra Lifesciences I, Ltd. v. Merck KGaA,* 331 F.3d 860, 865 (Fed. Cir. 2003) (emphasis added) (calling attention to the Court's decision in *Lilly*). In fact, there is nothing in the Court's opinion in *Lilly* that states or suggests that the 1984 Act was limited to the activities of generic drug companies.

In a similar vein, the majority's opinion also states:

> The meaning of the phrase "reasonably related" . . . is clearer in the context of the role of the 1984 Act in facilitating expedited approval of a generic version of a drug previously approved by the FDA. . . . As discussed above, the express objective of the 1984 Act was to facilitate the immediate entry of safe, effective generic drugs. . . upon expiration of a pioneer

> drug patent. . . . Therefore, the §271(e)(1) safe harbor clearly covers those pre-expiration activities "reasonably related" to acquiring FDA approval of a drug already on the market. . . . The exemption viewed in this context does not endorse an interpretation of §271(e)(1) that would encompass drug development activities far beyond those necessary to acquire information for FDA approval of a patented pioneer drug already on the market.

Integra, 331 F.3d at 866-67 (emphasis added).

While appearing to retreat from the original opinion's clear message that 271(e)(1) was only available for generic drug company activities, the errata made no substantive change. The Federal Circuit's decision, even as amended, may thus effectively deny any benefit of 271(e)(1) to one not intending to file an ANDA for FDA approval for a drug already on the market.

The majority's opinion in this regard is clearly contrary to the Court's precedent in *Lilly*, to the plain reading of the statute, to the promotion of human health, and even to the facilitation of the availability of generic drugs.

The Court also stated that 271(e)(1) "allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval." *Lilly,* 496 U.S. at 671. The Court did not limit the type of competitor to a generic drug competitor. The Court did not either limit the types of infringing activities – all activities necessary to obtain regulatory approval were countenanced by the Court.

In this case, Petitioner Merck's activities were

necessary to obtain regulatory approval. It was necessary in order to obtain regulatory approval to identify a molecule that would most likely be safe and effective in humans. One cannot obtain regulatory approval without first identifying the molecule for which approval is sought. Today, as when Merck carried out its studies, molecules can only be identified by making them and testing them. Such molecules cannot be identified merely by philosophical contemplation or by computerized predictions. Instead, many potential candidates, typically many hundreds or thousands, have to be made and tested in a laboratory before the single molecule that by all measures is the one most likely to be safe and effective in humans is declared to be "the" candidate for clinical studies. This process of trial and error takes many years.

The majority also concluded Merck's activities were not "reasonably related" to the development and submission of information to the FDA because the majority accepted as true the statement that the "Scripps-Merck experiments did not supply information for submission to the United States Food and Drug Administration (FDA)." *Integra*, 331 F.3d at 865-66. However, this statement is erroneous, since the experiments identified the active agent that would have been included in any submission to the FDA. The experiments did indeed supply information for submission to the FDA – the identity of the active agent!

An exemption under 271(e)(1) covering non-clinical activity is appropriate in view of not only the uncertainty of pre-clinical activities and FDA requirements, but also to encourage innovative medical cures, and to prevent extension of patent rights beyond expiration. The majority's evident concern that the exemption not "swallow the whole benefit of the Patent Act for some categories of

biotechnological inventions" does not justify the undermining of the legislative purpose of the statute. *Id.* at 867.

The majority's opinion relies heavily on selected portions of the legislative history that, frankly, cut both ways. However, the legislative history relied upon most heavily by the majority panel conflicts with the Court's own precedent in *Lilly*. For example, the majority comments:

> The House Committee that initiated this provision expressly described the pre-market approval activity as "a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute." The Committee further characterized the limits of this provision, noting that the "nature of the interference with the rights of the patent holder" would not be "substantial," but "de minimus [sic]." Thus, the 1984 Act was "designed to benefit the makers of generic drugs, research-based pharmaceutical companies, and not incidentally the public."

Id. at 865 (citations omitted).

However, a more pertinent portion of the legislative history of 35 U.S.C. § 271(e)(1) *supports* a construction of the statute that would allow for exempting pre-clinical activities. H.R. REP. NO. 98-957 p. 45 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647 (Section 271(e)(1) provides that it shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a federal

law which regulates the approval of drugs. This section does not permit commercial sale of a patented drug by the party using the drug to develop such information, but it does permit the commercial sale of research quantities of active ingredient to such party. The information which can be developed under this provision is the type required to obtain approval of the drug. A party which develops such information, but decides not to submit the application for approval, is protected as long as the development was done to determine whether or not an application for approval would be sought).

The Supreme Court has affirmatively stated that the statute applies to more than just generic drugs. The Court stated, "All of the products eligible for a patent term extension under § 201 [§ 156] are subject to § 202 [§ 271(e)(1)], since all of them--medical devices, food additives, color additives, new drugs, antibiotic drugs, and human biological products--are subject to premarket approval under various provisions of the FDCA . . . ." *Lilly,* 496 U.S. at 674. In considering whether the *de minimis* nature of the infringement mattered the Court stated, "Even if the competitive injury caused by the noninfringement provision is *de minimis* with respect to most drugs, surely it is substantial with respect to some of them -- so the 'serious constitutional question' (if it is that) is not avoided by petitioner's construction either." *Id.* at 679 n.7. The desire to speed new drugs and devices to market trumps the magnitude of the infringement in these types of cases. Thus, the Federal Circuit majority's reasoning and interpretation of the 271(e)(1) exemption is in direct conflict with controlling precedent from the U.S. Supreme Court.

B. Non-Clinical Activities Are Reasonably Related to the Development and Submission of Information Under a Federal Law Which Regulates the Approval of Drugs.

In support of its holding that Merck's sponsored pre-clinical development activities are not exempted from infringement under 35 U.S.C. 271(e)(1), the Federal Circuit states that such activities are "not 'solely for uses reasonably related' to clinical tests for the FDA." *Integra*, 331 F.3d at 866 (emphasis added). This is an erroneous reading of the statute. Rather, 271(e)(1) exempts from infringement uses of "a patented invention . . . reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. 271(e)(1). There is no requirement that the "information under a Federal law" be clinical data. The infringing acts must be "solely" for the exempt use, but, to be exempt, a use need only be "reasonably related" to the stated objective – development and submission of information to the FDA. Such information comprises both clinical and pre-clinical information.

It is well-settled that the phrase "reasonably related" within the context of 271(e)(1) provides latitude for the drug developer to engage in a wide variety of activities in the course of the drug development process.

> We infer that the phrase "reasonably related" . . . as used in §271(e)(1) reflects Congress' acknowledgement that it will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will take to win that

> agency's approval. Thus, Congress used this phrase to communicate its intention that the courts give parties some latitude in making judgments about the nature and extent of the otherwise infringing activities they would engage in as they sought to develop information to satisfy the FDA.

Intermedics, 775 F. Supp. at 1280. The test is prospective, in that it evaluates the potential infringer's activities at the time they were undertaken, and objective, in that it does not concern itself with the potential infringer's state of mind. *See Amgen,* 3 F. Supp. 2d 104.

As part of the rationale for its holding, the Federal Circuit characterizes the work performed by Scripps as "general biomedical research to identify new compounds." The Federal Circuit stated the FDA has no interest in the "hunt for drugs" and, thus, the use was not reasonably related to clinical testing.

Since this Court first addressed section 271(e)(1), courts have been reluctant to limit the scope of research and development activities that are "reasonably related" to FDA approval in the manner suggested by the Federal Circuit. *See, e.g., Lilly,* 496 U.S. 661; *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992). At the very least, activities to generate information for Investigational New Drug ("IND") submissions must be covered by the exemption. There is a significant amount of pre-clinical information required for approval of an IND, including, most essentially, the identity of the molecule whose safety and efficacy in humans is to be tested. Additionally, the regulations require the applicant to provide information regarding a drug's pharmacological class, a summary of the pharmacokinetic and toxicological

effects in animals or *in vitro*, and any information that would aid in the evaluation of the proposed clinical trials with respect to safety or their design. *See* 21 C.F.R. §§ 312.23(a)(3)(i), 312.23(a)(5)(ii), 312.23(a)(5)(iii), 312.23(a)(10)(iv). Further, the FDA can require "any other relevant information needed for review of the application." 21 C.F.R. § 312.23(a)(11).

The record shows Merck's and Scripp's activities were specifically tailored for IND submission, the purpose of the contract was for conducting late-stage pre-clinical development studies with the intent to enter clinical trials within three years and a limited number of compounds were actually tested during the collaboration. The Federal Circuit does not distinguish between the different types of pre-clinical development activities conducted during development, but simply holds that none of the activities are entitled to the safe harbor. However, the FDA clearly views focused pre-clinical activity as part of the process to obtain marketing approval.

The process begins long before any submission of information to the FDA and is an expensive and risky enterprise. An FDA Consumer Special Report explains this process. In it, the FDA tells the story of new drug development in the United States, stating that "[t]he research process is a complicated, time-consuming and costly one whose end result is never known at the outset." Jeffrey P. Cohn, *The Beginnings: Laboratory and Animal Studies*, FDA CONSUMER SPECIAL REPORT FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES, Jan. 1995, http://www.fda.gov/fdac/special/newdrug/begin.html. The FDA estimates that this research process averages eight-and-a-half years and includes early laboratory and animal

testing, as well as later clinical trials using human subjects. The FDA breaks out the research process into two major phases – (i) preclinical research, all activities done prior to testing in human subjects, that may help demonstrate safety and efficacy, and (ii) clinical research, the direct testing of safety and efficacy in humans. Results and underlying information relating to both phases of research must be submitted to the FDA for consideration. Only after the FDA is convinced by the weight of the evidence does it approve the commercial sale of a pharmaceutical for the treatment of specific disorders.

If the exemption covers only clinical activity, the Federal Circuit panel undercuts and delays not just innovative drug development, but restricts certain aspects of generic drug development and drugs developed under 21 U.S.C. § 355(b)(2) ("505(b)(2)") that the Supreme Court has already suggested is exempt from infringement. *Lilly*, 496 U.S. at 570. For example, in confirming that the 271(e)(1) exemption applies to both ANDA and 505(b)(2) applicants, the Supreme Court implies that even the pre-clinical development work that may be required of a 505(b)(2) applicant or a generic drug falling under 21 U.S.C. § 355(j)(2)(C) would benefit from the safe harbor. If the Federal Circuit indeed holds that no type of pre-clinical testing is exempt from infringement under 271(e)(1), then any time a generic drug applicant is required to conduct pre-clinical tests to support an approval of its ANDA or 505(b)(2) application, then those pre-clinical tests will not be exempt from an infringement claim. While it is probably not the intent of the Federal Circuit to expose these applicants to infringement, there is no rational basis to apply the exemption to ANDA and 505(b)(2) applicants when the same sort of information is not exempt when filed in support of an IND or a new drug

application filed under 21 U.S.C. §355(b)(1). However, if the Federal Circuit's holding is to be interpreted in a consistent way, then it runs counter to Supreme Court precedent as set forth in *Lilly* as well as Congressional intent.

A goal in enacting 35 U.S.C. § 271(e)(1) was to enable competitive products to reach the marketplace as early as possible. H.R. REP. NO. 98-957 p. 15. Allowing pioneering drug companies to operate under this provision for all activities related to new drug approval, both pre-clinical and clinical, is consistent with this goal.

C. The Lower Court's Decision Effects a *de facto* Extension of Patent Term – Precisely What Congress Intended to Prevent by Enacting 35 U.S.C. § 271(e)(1).

There was a day when rigid patent enforcement prevented the initiation by competitors of any activities required to obtain FDA approval until the patent expired. The effect of such rigid patent enforcement was to delay the launch of competing products for the time it took a competitor to carry out its pre-clinical and clinical work, prepare and file its drug application, and receive FDA approval. The delay was typically measured in years. The delay effectively extended the marketing exclusivity of the patent holder, and this was perceived an improper, *de facto* extension of the term of the patent right.

However, this regime of rigid patent enforcement was interred by the 1984 Act, and its resurrection has been thwarted by subsequent judicial rulings, until the Federal Circuit's in *Integra*. The Federal Circuit held that Petitioner Merck's pre-clinical activities, carried out to

identify which molecule would be taken forward for clinical testing, were not protected under 35 U.S.C. §271(e)(1). *Integra*, 331 F.3d at 872.

The effect of the majority's opinion is a *de facto* extension of the term of some patents. Consider, for example, a patent covering a protein product that has already been approved and is on the market. A broad genus claim covering the protein may very well contain proteins having improved properties. (The same situation could arise for non-protein drugs.) Yet, under one interpretation of the majority's rule, no activities directed toward discovering an improved drug that is covered by the patent may be carried out until after the patent expires.

If the initiation of discovery begins only after the patent expires, then a product utilizing an improved protein could not be launched for many years after patent expiry (at least five years and more likely seven to ten years or more, considering the time it takes to discover an improved molecule suitable to be a drug candidate, to conduct pre-clinical and clinical studies, and to receive FDA approval). Under these circumstances, the patentee's product will be effectively free from competition from a competing, improved product for a period of five to ten years or more – a *de facto* extension of the original drug's patent.

The Court characterized such a *de facto* extension of patent term as a "distortion" and recognized that Congress expressly intended to eliminate that distortion through enactment of 271(e)(1). *Lilly*, 496 US at 670-71. The only way to accomplish Congress' purpose of eliminating *de facto* patent extensions is to not draw artificial lines, as the Federal Circuit majority has done, between generic and non-generic activities, between pre-clinical and clinical

activities, and between discovery and post-discovery activities.

D. The Lower Court's Decision Will Delay or Prevent the Discovery and Development of Innovative Therapies, and Thereby Also Delay or Prevent Subsequent Generic Equivalents.

The Supreme Court stated, "The monopoly privileges that Congress may authorize are neither unlimited nor primarily designed to provide a special private benefit . . . [and] . . . makes reward to the owner a secondary consideration". *Sony,* 464 U.S. at 429. The public is best served when there is increased and speedy access to new drugs. This is especially true in areas where there are clearly unmet medical needs such as with AIDS, Alzheimer's disease, and aggressive malignant cancers.

If both pre-clinical and clinical activities for new drugs do not fall within the 271(e)(1) safe harbor, patients will be deprived of timely access to many life-saving innovative products. Forcing lengthy negotiations and expensive licenses early in the new drug process before even understanding whether a drug has a desirable activity, let alone whether it is safe and efficacious in the clinic, will result in decisions not to pursue many of these products. This is especially true given that only 1 in 10000 compounds ever make it to the market.

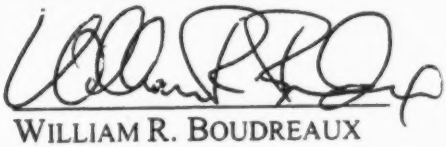
This is a significant risk when a patent holder, possibly a direct competitor, is unwilling to license basic enabling technology. In such a case, the drug developer must wait until patent expiration to initiate development activities. This inhibits innovation and could, in some cases, delay

launch of life-saving medicines up to twenty years. It likewise will delay in some cases the entry of equivalent and more generally affordable generic products. This runs counter to Congressional intent and harms the public's interest in the swift provision of innovative, improved, safe, and effective therapies.

CONCLUSION

For the foregoing reasons, *amicus curiae* Eli Lilly and Company respectfully requests that the Court grant *certiorari*.

Respectfully submitted,



WILLIAM R. BOUDREAUX
COUNSEL OF RECORD
JAMES J. KELLEY
COUNSEL FOR *AMICUS CURIAE*
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285